ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

1) Heading of the Part: Licensing of Radioactive Material

2) Code Citation: 32 Ill. Adm. Code 330

3)

Section Number:	Proposed Action:
330.20	Amendment
330.40	Amendment
330.220	Amendment
330.240	Amendment
330.260	Amendment
330.270	Amendment
330.280	Amendment
330.320	Amendment
330.330	Repealed
330.400	Amendment
330.APPENDIX A	Amendment
330.APPENDIX C	Amendment

4) Statutory Authority: Implementing and authorized by Section 10 of the Radiation Protection Act of 1990 [420 ILCS 40/10].

5) Effective Date of Amendments:

6) Does this rulemaking contain an automatic repeal date? No

7) Does this rulemaking contain incorporations by reference? No

8) A copy of the adopted amendments, including any material incorporated by reference is on file at the Agency's headquarters located at 1035 Outer Park Drive, Springfield, Illinois and is available for public inspection

9) Notice of Proposal Published in the Illinois Register: 34 Ill. Reg. 17022; November 12, 2010

10) Has JCAR issued a Statement of Objections to these Amendments? No

11) Differences between proposal and final version: Several grammatical and stylistic changes were made in accordance with JCAR's recommendation.

1. In Section 330.40 c)A)iv through viii), restored "microCi"
2. In Section 330.40 c)A)vii), restored "microGy"
3. In Section 330.40 c)B), restored "microCi"
4. In Section 330.40 c)D)ii through vi), restored "microCi"
5. In Section 330.220 a)2), restored "microCi"
6. In Section 330.220 b)3)B)ii, restored "microCi" twice
7. In Section 330.220 h)3)D) changed "340.1080" to "340.1010(a)"
8. In Section 330.260 c)17) restored formatting
9. In Section 330.APPENDIX A, restored "microCi"

12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreement letter issued by JCAR? This is an exempt rulemaking; no agreements were made.

13) Will these amendments replace an emergency rule currently in effect? No

14) Are there any amendments pending on this Part? Yes

15) Summary and Purpose of amendments: This proposed amendment will clarify the documentation required by the Agency for approval of an authorized nuclear pharmacist. It will also update and clarify general licenses and license exemptions and requirements for manufacture and distribution of radioactive material. In addition, it will clarify standards for regulation of discrete sources of radium-226, accelerator-produced radioactive material, and discrete sources of naturally occurring radioactive material as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the Atomic Energy Act of 1954 definition of *Byproduct material* to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, or any discrete source of naturally occurring radioactive material other than source material.

These proposed amendments will ensure compatibility with the U.S. Nuclear Regulatory Commission's 10 CFR 30, 32, and 35 regulations currently in place for use of radioactive materials. Agreement States such as Illinois are required to have these changes in place by October 29, 2010. NRC has assigned this rulemaking a compatibility category of B. This means that the Illinois rule must have language essentially identical to NRC's because of transboundary considerations.

Section 31 of the Radiation Protection Act of 1990 [420 ILCS 40/31] provides that the Agency is exempt from rulemaking procedures in the Illinois Administrative Procedure Act when regulations that are identical in substance are necessary to implement, secure,

or maintain federal authorization for a program. After consideration of comments from the appropriate federal agency, the Agency may adopt the verbatim text of the laws, regulations, or orders as necessary and appropriate for authorization or maintenance of the program. The NRC has reviewed the proposed amendments and has indicated that these amendments are needed to ensure compatibility with 10 CFR 30, 32, and 35. Because this rulemaking is not subject to the Illinois Administrative Procedure Act, and in accordance with Section 31, this rulemaking will become effective following the first notice period immediately upon filing for adoption with the Secretary of State or at a date required or authorized by the relevant federal laws, regulations, or orders as stated in the notice of the rulemaking, and shall be published in the Illinois Register.

16) Information and questions regarding these adopted amendments shall be directed to:

Louise Michels
Staff Attorney
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, Illinois 62704
(217) 785-9876

The full text of the Adopted Amendments begin on the next page:

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION

PART 330
LICENSING OF RADIOACTIVE MATERIAL

SUBPART A: GENERAL PROVISIONS

SUBPART B: TYPES OF LICENSES

SUBPART C: SPECIFIC AND GENERAL LICENSES

AUTHORITY: Implementing and authorized by the Radiation Protection Act of 1990 [420 ILCS 40].

SOURCE: Filed April 20, 1974, by the Department of Public Health; transferred to the Department of Nuclear Safety by P.A. 81-1516, effective December 3, 1980; amended at 5 Ill.

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Reg. 9586, effective September 10, 1981; codified at 7 Ill. Reg. 17492; recodified at 10 Ill. Reg. 11268; amended at 10 Ill. Reg. 17315, effective September 25, 1986; amended at 15 Ill. Reg. 10632, effective July 15, 1991; amended at 18 Ill. Reg. 5553, effective March 29, 1994; emergency amendment at 22 Ill. Reg. 6242, effective March 18, 1998, for a maximum of 150 days; amended at 22 Ill. Reg. 14459, effective July 27, 1998; amended at 24 Ill. Reg. 8042, effective June 1, 2000; amended at 27 Ill. Reg. 5426, effective March 17, 2003; recodified from the Department of Nuclear Safety to the Illinois Emergency Management Agency at 27 Ill. Reg. 13641; amended at 30 Ill. Reg. 8928, effective April 28, 2006; amended at 32 Ill. Reg. 6462, effective April 7, 2008; amended at 32 Ill. Reg. 9199, effective June 13, 2008; amended at 33 Ill. Reg. 4918, effective March 23, 2009; amended at 35 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 330.20 Definitions

"Authorized nuclear pharmacist" means a pharmacist who:

Meets the requirements in Section 330.260(c)(18), ~~(c)~~(19) and ~~(c)~~(21) ~~of this Part~~; or

Is identified as an authorized nuclear pharmacist on:

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

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

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

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

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

Is designated as an authorized nuclear pharmacist in accordance with Section 330.260(c)(16) ~~of this Part~~.

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a medical facility.

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"General license" *means a license*, as set forth in this Part and 32 Ill. Adm. Code 341, which is *effective without the filing of an application to transfer, acquire, own, possess or use quantities of, or devices or equipment utilizing, radioactive material* [420 ILCS 40/4(d)], although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of 32 Ill. Adm. Code: Chapter II and any limitations of the general license.

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

"Protective actions" means actions taken by members of the public to protect themselves from radiation from an incident involving radioactive material, which may include sheltering, evacuation, relocation, control of access, administration of radiation-protective drugs, decontamination of persons, decontamination of land or property, or control of food or water.

"Specific license" means a license, issued after application, to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, radioactive materials [420 ILCS 40/4(m)]. The licensee is subject to all applicable portions of 32 Ill. Adm. Code: Chapter II, as well as any limitations specified in the licensing document.

(Source: Amended at 35 Ill. Reg. _____, effective _____)

Section 330.40 License Exemption − Radioactive Materials Other Than Source Material

a) Exempt Concentrations

1) Any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this Part provided they have been introduced or transferred~~distributed pursuant to a license~~ as described in subsection (a)(2) or (3)~~of this Section~~. This Section shall not be deemed to authorize the import of radioactive materials or products containing radioactive materials.

2) 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 subsection (a)(1) ~~of this Section~~ or equivalent regulations of the U.S. Nuclear Regulatory Commission (10 CFR 30.14) or~~,~~ an Agreement State~~ or a Licensing State~~, except in accordance with a specific license issued pursuant to Section 330.280(a)~~. of this Part or the general license provided in Section 330.900 of this Part.~~

3) A manufacturer, processor or producer of a product or material is exempt from the requirements for a license set forth in this Part to the extent that person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Appendix A and introduced into the product or material by a licensee holding a specific license issued by the Agency expressly authorizing that 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.

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b) Exempt Quantities

1) Except as restricted by subsections (b)(2) through (4), any~~Any~~ person is exempt from this Part 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 Appendix B ~~of this Part provided they have been distributed pursuant to a license as described in subsection (b)(3) of this Section~~. Furthermore, any person is exempt from this Part to the extent that person possesses, uses, transfers or owns radioactive material that was received or acquired before September 25, 1971, under the general license then provided by the regulations of the U.S. Atomic Energy Commission (10 CFR 31.4) or the equivalent regulations of an Agreement State.

AGENCY NOTE: Capsules distributed pursuant to 10 CFR 32.21 that contain carbon-14 urea are only authorized for "in-vivo" diagnostic use for humans. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license from the Agency. Nothing in this Section relieves persons from complying with applicable Federal and State requirements governing receipt, administration and use of drugs.

2) This subsection (b) 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.

3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this Part, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this subsection (b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or an Agreement State ~~or a Licensing State~~, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.18 or 32.21, or by the Agency pursuant to Section 330.280(b) ~~of this Part~~, which states that the radioactive material may be transferred by the licensee to persons exempt under this subsection (b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~.

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4) No person shall, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by the exemption in subsection (b)(1) so that the aggregate quantity exceeds the limits set forth in Appendix B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by this Part.

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

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c) Exempt Items

1) 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, any person is exempt from this Part to the extent that he receives, possesses, uses, transfers, owns or acquires the following products:

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

A) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

i) 925 MBq (25 mCi) of tritium per timepiece;

ii) 185 MBq (5 mCi) of tritium per hand;

iii) 555 MBq (15 mCi) of tritium per dial (bezels when used shall be considered as part of the dial);

iv) 3.7 MBq (100 microCi) of promethium-147 per watch or 7.4 MBq (200 microCi) of promethium-147 per any other timepiece;

v) 740 kBq (20 microCi) of promethium-147 per watch hand or 1.48 MBq (40 microCi) of promethium-147 per other timepiece hand;

vi) 2.22 MBq (60 microCi) of promethium-147 per watch dial or 4.44 MBq 1(20 microCi) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

vii) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber: for wrist watches, 1 microGy (100 microrad) per hour at 10 centimeters from any surface; for pocket watches, 1 microGy (100 microrad) per hour at 1 centimeter from any surface; for any other timepiece, 2 microGy (200 microrad) per hour at 10 centimeters from any surface; or

viii) 37 kBq (1 microCi) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007~~acquired prior to May 1, 1974~~.

~~B)~~ ~~Lock illuminators containing not more than 555 MBq (15 mCi) of tritium or not more than74 MBq (2 mCi) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 10 microGy (1 mrad) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~

B~~C~~) Precision balances containing not more than 37 MBq (1 mCi) of tritium per balance or not more than 18.5 MBq (500 microCi) of tritium per balance part manufactured before December 17, 2007.

~~D)~~ ~~Automobile shift quadrants containing not more than 925 MBq (25 mCi) of tritium.~~

C~~E~~) Marine compasses containing not more than 27.8 GBq (750 mCi) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 mCi) of tritium gas manufactured before December 17, 2007.

~~F) Thermostat dials and pointers containing not more than 925 MBq (25 mCi) of tritium per thermostat.~~

D~~G~~) Electron tubes; provided that each tube does not contain more than one of the following specified quantities of radioactive material:

i) 5.55 GBq (150 mCi) of tritium per microwave receiver protector tube or 370 MBq (10 mCi) of tritium per any other electron tube;

ii) 37 kBq (1 microCi) of cobalt-60;

iii) 185 kBq (5 microCi) of nickel-63;

iv) 1.11 MBq (30 microCi) of krypton-85;

v) 185 kBq (5 microCi) of cesium-137; or

vi) 1.11 MBq (30 microCi) of promethium-147;

and provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 10 microGy (1 mrad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.

AGENCY NOTE: For purposes of subsection (c)(1)(D)~~(e)(1)(G) of this Section~~, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.

E~~H~~) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

i) Each source contains no more than one exempt quantity set forth in Appendix B ~~of this Part~~; and

ii) Each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's sources may contain one or more radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B ~~of this Part~~, provided that the sum of such fractions shall not exceed unity.

AGENCY NOTE: For purposes of subsection (c)(1)(E) ~~(c)(1)(H) of this Section~~, 1.85 kBq (50 nCi) of americium-241 is considered an exempt quantity.

~~I)~~ ~~Spark gap irradiators containing not more than 37 kBq (1 microCi) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 11.4 liters (3 gallons) per hour.~~

2) Self-Luminous Products Containing Radioactive Material

A) Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license, issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this subsection (c)(2)(A) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments. The U. S. Nuclear Regulatory Commission shall make this determination of exemption.

B) Radium-226. Any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers or owns

articles containing less than 3.7 kBq (100 nCi) of radium-226 which were acquired prior to May 1, 1974.

3) Gas and Aerosol Detectors Containing Radioactive Material

A) Except for persons who manufacture, process, produce or initially transfer for sale and distribution gas and aerosol detectors containing radioactive material, any person is exempt from 32 Ill. Adm. Code: Chapter II, Subchapters b and d to the extent that such person receives, possesses, uses, transfers, owns or acquires ionization chamber smoke detectors containing not more than 37 kBq (1 µCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires. The detectors ~~radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material~~ shall have been manufactured, imported or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.26 that~~or a Licensing State pursuant to Section 330.280(c) of this Part, which~~ authorizes ~~the~~ transfer of the detectors to persons who are exempt from regulatory requirements.

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

B) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State or a former Licensing State shall be considered exempt under subsection (c)(3)(A)~~ of this Section~~, provided that the device is labeled in accordance with the specific license ~~authorizing distribution of the generally licensed device~~ and provided further that it meets~~they meet~~ the requirements of 10 CFR 32.26 in effect at the time of distribution.~~Section 330.280(c) of this Part.~~

~~C)~~ ~~Gas and aerosol detectors containing naturally-occurring or accelerator-produced radioactive material (NARM) previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under subsection (e)(3)(A) of this Section, provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of Section 330.280(e) of this Part.~~

~~4)~~ ~~Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Department or an Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in 10 CFR 32.17 published January 1, 1997, exclusive of subsequent amendments or editions. This exemption does not authorize the manufacture of any resins containing scandium-46.~~

(Source: Amended at 35 Ill. Reg. _____, effective _____)

SUBPART B: TYPES OF LICENSES

Section 330.220 General Licenses − Radioactive Material Other Than Source Material

a) Certain Devices and Equipment

1) A general license is hereby issued to transfer, receive, acquire, possess and use radioactive material incorporated in the following devices or equipment that has been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90, 340, 341 and~~,~~ 400 and Sections 330.40(a)(2), 330.310, 330.400 and 330.500 of this Part.

AGENCY NOTE: Attention is directed particularly to the provisions of 32 Ill. Adm. Code 340 that relate to the labeling of containers.

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

b) Certain Measuring, Gauging or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere

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 receive, acquire, possess, use or transfer, in accordance with the provisions of subsections (b)(2) through (9) ~~of this Section~~, 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 or quantitative chemical composition, or for producing light or an ionized atmosphere.

2) The general license provided by subsection (b)(1) ~~of this Section~~ applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to Section 330.280(d) ~~of this Part~~ or in accordance with the specifications contained in an equivalent specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a former Licensing State. The devices shall have been received from a specific licensee described in this subsection (b)(2) or through a transfer made under subsection (b)(3)(L) ~~of this Section~~.

AGENCY NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling that is found in 21 CFR 179.21.

3) Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license described in subsection (b)(1) of this Section:

A) 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 on the device and shall comply with all instructions and precautions provided by such labels;

B) Shall assure that the device is tested for leakage of, or contamination by, radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified on the device labels; however:

i) A device containing only krypton need not be tested for leakage of, or contamination by, radioactive material; and

ii) A device containing only tritium or not more than 3.7 MBq (100 microCi) of other beta and/or gamma emitting material or 370 kBq (10 microCi) of alpha emitting material or a device held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

C) Shall assure that testing (including testing required by subsection (b)(3)(B) ~~of this Section~~), installation, servicing and removal from installation involving the radioactive material, its shielding or containment is performed:

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

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

D) Shall maintain records showing compliance with the requirements

of subsections (b)(3)(B), (C) and (H) and (b)(6)(B) ~~of this Section~~. The records shall show the results of tests. The records shall also show the dates of performance of, and the names of persons performing, physical inventories, testing, installation, servicing and removal from installation of radioactive material or its shielding or containment. Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license provided by subsection (b)(1) ~~of this Section~~ shall retain these records as follows:

i) A record of a test of an on-off mechanism and indicator or a test for leakage or contamination performed in accordance with subsection (b)(3)(B) ~~of this Section~~ shall be retained for 5 years after the next required test is performed or until the device is transferred or disposed of; and

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ii) A record of testing, installation, servicing or removal from installation performed in accordance with subsection (b)(3)(C) ~~of this Section~~ shall be retained for 5 years from the date of the recorded event or until the device is transferred or disposed of; and

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iii) A record of transfer or disposal of a device in accordance with subsection (b)(3)(H) ~~of this Section~~ shall be retained for 5 years from the date of the recorded event; and

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AGENCY NOTE: Note that this record must be retained after transfer of the device.

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iv) A record of a quarterly physical inventory performed in accordance with subsection (b)(6)(B) ~~of this Section~~ shall be retained for 5 years after the next required test is performed or until the device is transferred or disposed of;

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E) Shall immediately suspend operation of the device if there is a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 Bq (5 nano~~μ~~Ci) or more removable radioactive material. The device

shall not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ to repair such devices. The device and any radioactive material from the device shall be disposed of only by transfer to a person authorized by an applicable specific license to receive the radioactive material in the device or as otherwise approved by the Agency. A report containing a brief description of the event and the remedial action taken shall be furnished to the Agency within 30 days. As applicable, the following shall also be furnished to the Agency:

i) A report within 5 days (as required by 32 Ill. Adm. Code 340.1260) if detection of 185 Bq (5 nano~~μ~~Ci) or more removable radioactive material indicates that a sealed source is leaking or contaminated; and

ii) A plan within 30 days for ensuring that the person's premises and environs are acceptable for unrestricted use if 185 Bq (5 nano~~μ~~Ci) or more removable radioactive material is detected on the device or failure of or damage to a source is likely to result in contamination of the premises or the environs;

F) Shall not abandon the device containing radioactive material;

G) Shall not export the device containing radioactive material except in accordance with 10 CFR 110, published at 73 Fed. Reg. 78615, December 23, 2008~~as applicable, effective July 21, 2005~~, exclusive of subsequent amendments or editions;

H) Shall transfer or dispose of the device containing radioactive material only:

i) By export as provided by subsection (b)(3)(G)~~ of this Section~~;

ii) By transfer to another general licensee as provided by subsection (b)(3)(L)~~ of this Section~~;

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iii) By transfer to a person authorized to receive the device by a specific license issued by the Agency pursuant to Section 330.280(d) ~~of this Part~~ or an equivalent specific license issued by the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~;

iv) By transfer to a person authorized to perform waste collection by a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~; or

v) As approved under subsection (b)(3)(K) ~~of this Section~~;

I) Shall furnish a written report to the Agency within 30 days after transferring~~,~~ ~~or~~ disposing of or redesignating the device containing radioactive material. The~~Such~~ notification shall include:

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

ii) The name, address and license number of the transferee (license number not applicable if exported);

iii) A receipt from the transferee showing the serial number of the device and the date that it was received (not applicable if exported or redesignated);

AGENCY NOTE: Subsection (b)(3)(O) of this Section provides information about redesignation of administrative control over a device.

J) Shall maintain a record of the transfer or disposal of the device as required by subsection (b)(3)(D)(iii) ~~of this Section~~;

K) Shall obtain written approval from the Agency before transferring the device to a transferee not identified in subsections (b)(3)(H)(i) through (iv) ~~of this Section~~;

L) Shall transfer the device to another general licensee only if:

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i) The device remains in use at a particular location. In such case the transferor shall give the transferee a copy of subsection (b) ~~of this Section~~, a copy of 32 Ill. Adm. Code 310.40, 310.80, 330.310, 330.500, 340.1210, 340.1220, 340.1260 and any safety documents identified in the device labels; or

ii) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use;

M) Shall furnish a report to the Agency within 30 days after transferring a device containing radioactive material as provided by subsection (b)(3)(L)(i) ~~of this Section~~. The~~Such~~ notification shall include:

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

ii) The transferee's name and mailing address;

iii) The address of the transferee's location of use or storage of the device; and

iv) The name, title and phone number of the responsible individual identified by the transferee in accordance with subsection (b)(3)(N) ~~of this Section~~ to have knowledge of, and authority to take actions to ensure compliance with, the appropriate regulations and requirements;

N) 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 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;~~.~~

O) May redesignate a device to be possessed and used under its own specific license without prior approval if the person:

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i) Verifies that the specific license authorizes possession and use of the device or applies for and obtains an amendment to the license authorizing the possession and use;

ii) Removes, alters, covers or clearly and unambiguously augments the existing label required by subsection (b)(3)(A) so that the device is labeled in compliance with 32 Ill. Adm. Code 340.910; however, the manufacturer, model number and serial number shall be retained;

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

iv) Reports the new designation as required by subsection (b)(3)(I).

4) Any person who receives, acquires, possesses or uses a device identified in subsection (b)(4)(A) ~~of this Section~~ shall register with the Agency in accordance with subsection (b)(4)(B) ~~of this Section~~:

A) A person shall register with the Agency if the person receives, acquires, possesses or uses any of the following devices pursuant to the general license described in subsection (b)(1) ~~of this Section~~:

i) An electron capture detector, gauge or x-ray fluorescence analyzer containing a sealed source equal to or greater than 37 MBq (1 mCi) of radioactive material;

ii) A device containing a sealed source equal to or greater than 3.7 MBq (100 µCi) of strontium-90 or radium-226; or

iii) A static control or measuring device containing a sealed source equal to or greater than 37 MBq (1 mCi) of radioactive material other than polonium-210 or radium-226;

B) A person shall register with the Agency no later than 30 days after

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receiving a device identified in subsection (b)(4)(A) ~~of this Section~~. Registration information shall be in a format prescribed by the Agency and furnished in accordance with subsection (b)(4)(C) ~~of this Section~~;

C) When registering with the Agency, a person shall furnish the following and any other information requested by the Agency to track the location and use of a device:

i) The name and mailing address of the person;

ii) The name, title and phone number of the responsible individual designated by the person in accordance with subsection (b)(3)(N) ~~of this Section~~ as having knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements;

iii) Information about each device meeting the criteria of subsection (b)(4)(A) ~~of this Section~~. This information shall include the manufacturer (or initial transferor), model, serial number, radionuclide and activity as indicated on the labels, the location of the device within the radiation installation, and the calendar quarter and year the person received the device;

iv) The addresses of the locations of use or storage of the devices reported under subsection (b)(4)(C)(iii) ~~of this Section~~;

AGENCY NOTE: For portable devices, these are the addresses of the primary places of storage.

v) Certification by the responsible individual that the information about devices was verified through a physical inventory and examination of label information; and

vi) Certification by the responsible individual that the general licensee is aware of the requirements of the general license;

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AGENCY NOTE: Fee requirements for general licenses are in 32 Ill. Adm. Code 331. Reporting requirements are in Section 330.310(b) ~~of this Part~~, and bankruptcy notification requirements are in Section 330.310(j) ~~of this Part~~.

D) Any person who is required by subsection (b)(4) ~~of this Section~~ to register with the Agency shall report a change in mailing address or address of location of use or storage. This report shall be furnished to the Agency within 30 days after the change.

AGENCY NOTE: For portable devices, this is the address of the primary place of storage.

5) A person from out of state who is generally licensed by the U.S. Nuclear Regulatory Commission ~~or~~, an Agreement State ~~or a Licensing State~~ with respect to a device identified in subsection (b)(4)(A) ~~of this Section~~ is exempt from the registration requirement in subsection (b)(4) ~~of this Section~~ if the device is used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year.

6) Any person who receives, acquires, possesses or uses radioactive material in a device under the general license described in subsection (b)(1) ~~of this Section~~ shall limit storage of a device that is not in use to a maximum of 2 years.

A) If a device with a shutter is not being used, the shutter shall be locked in the closed position. Testing for proper operation of the on-off mechanism and indicator is not required during the storage period. However, the on-off mechanism and indicator shall be checked before the device is returned to service if the device has not been tested within the required test interval. Tests for leakage of, or contamination by, radioactive material shall be conducted during the storage interval as required by subsection (b)(3)(B) ~~of this Section~~.

B) A device kept in standby for future use is exempt from the 2-year storage limit if the person performs a quarterly physical inventory of the device while it is in standby. The requirements and exemption of subsection (b)(6)(A) ~~of this Section~~ shall apply.

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AGENCY NOTE: Record keeping requirements are contained in subsection (b)(3)(D) ~~of this Section~~.

7) Failure of any person to comply with the requirements of this subsection (b) ~~of this Section~~ may cause the Agency to impose civil penalties in accordance with 420 ILCS 40/36 and 32 Ill. Adm. Code 200.

8) The general license described in subsection (b)(1) ~~of this Section~~ does not authorize the manufacture of devices containing radioactive material.

9) The general license described in subsection (b)(1) ~~of this Section~~ is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90, 326, 331, 340.1210, 340.1220, 340.1260, and 341 and Sections 330.310 and 330.500 of this Part. Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license described in subsection (b)(1) of this Section is exempt from the requirements of 32 Ill. Adm. Code 400 and 340 except for the Sections of 32 Ill. Adm. Code 340 specifically identified in subsections (b)(3)(E) and (b)(9) of this Section.

c) Luminous Safety Devices for Aircraft

1) A general license is hereby issued to receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

A) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300 mCi) of promethium-147; and

B) 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 issued by the Department or an Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.53, published at 43 FR 6923, February 17, 1978~~January 1, 1998~~, exclusive of subsequent amendments or editions.

2) Persons who receive, acquire, possess or use luminous safety devices

pursuant to the general license in subsection (c)(1) of this Section are exempt from the requirements of 32 Ill. Adm. Code 340 and 400, except that they shall comply with the provisions of 32 Ill. Adm. Code 340.1210 and 340.1220.

3) This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium-147.

4) This general license does not authorize the receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

5) This general license is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90 and~~,~~ 341 and Sections 330.310, 330.400 and 330.500 of this Part.

d) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

e) Calibration and References Sources

1) A general license is hereby issued to those persons listed below to receive, acquire, possess, use and transfer, in accordance with the provisions of subsections (e)(4) and (5)~~ of this Section~~, americium-241 in the form of calibration or reference sources:

A) Any person who holds a specific license issued by the Agency that authorizes the licensee to receive, possess, use and transfer radioactive material; and

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

2) A general license is hereby issued to receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subsections (e)(4) and (5) ~~of this Section~~ to any person who holds a specific license issued by the Agency that authorizes the licensee to receive, possess, use and transfer radioactive material.

3) A general license is hereby issued to receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of subsections (e)(4) and (5) ~~of this Section~~ to any person who holds a specific license issued by the Agency that authorizes the licensee to receive, possess, use and transfer radioactive material.

4) The general licenses in subsections (e)(1) through (3) ~~of this Section~~ apply only to calibration or reference sources that 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 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, exclusive of subsequent amendments or additions, or 70.39, published at 43 Fed. Reg. 6925, February 17, 1978, exclusive of subsequent amendments or additions, or that have been manufactured in accordance with the specifications contained in a specific license issued by the Agency, an Agreement State or a former Licensing State pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, exclusive of subsequent amendments or additions, or 70.39, published at 43 Fed. Reg. 6925, February 17, 1978~~published January 1, 1998~~, exclusive of subsequent amendments or editions.

5) The general licenses provided in subsections (e)(1) through (3) ~~of this Section~~ are subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90, 340, 341 and~~,~~ 400 and Sections 330.310, 330.400 and 330.500 of this Part. In addition, persons who receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

A) Shall not possess at any one time, at any one location of storage or use, more than 185 kBq (5 µCi) of americium-241, 185 kBq (5 µCi) of plutonium or 185 kBq (5 µCi) of radium-226 in such sources;

B) Shall not receive, possess, use or transfer such source unless the source~~,~~ or the storage container~~,~~ bears a label that includes ~~one of~~ the following statement~~statements, as appropriate,~~ or a statement that contains the information called for in this ~~one of the~~ statement~~following statements, as appropriate~~:

~~i)~~ 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 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) (PLUTONIUM) (RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of Manufacturer or Importer

AGENCY NOTE: Showing only the name of the appropriate material.

~~ii)~~ ~~The receipt, possession, use and transfer of this source, Model ___ , Serial No. _____, are subject to a general license and the regulations of a Licensing State. Do not remove this label.~~

~~CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.~~

_____

~~Name of Manufacturer or Importer~~

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

D) Shall store the source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium or radium-226 that might otherwise escape during storage; and

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

6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium or radium-226.

f) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

AGENCY NOTE: The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections (f)(2) through (6)~~ of this Section~~, the following radioactive materials in prepackaged units 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:

A) Carbon-14, in units not exceeding 370 kBq (10 µCi) each.

B) Cobalt-57, in units not exceeding 370 kBq (10 µCi) each.

C) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 µCi) each.

D) Iodine-125, in units not exceeding 370 kBq (10 µCi) each.

E) Mock iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (50 nCi) of iodine-129 and 185 Bq (5 nCi) of americium-241 each.

F) Iodine-131, in units not exceeding 370 kBq (10 µCi) each.

G) Iron-59, in units not exceeding 740 kBq (20 µCi) each.

H) Selenium-75, in units not exceeding 370 kBq (10 µCi) each.

2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (f)(1) ~~of this Section~~ until he or she has filed the Agency form entitled "Certificate – In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of the form with certification number assigned. No person shall transfer a validated copy of the form to another person without prior written consent of the Agency. The following information shall be furnished to the Agency on the form entitled "Certificate – In Vitro Testing with Radioactive Material Under General License":

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

B) The location of use; and

C) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in subsection (f)(1) ~~of this Section~~ and that the~~such~~ tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subsection (f)(1) ~~of this Section~~ shall comply with the following:

A) The general licensee shall not possess at any one time, pursuant to the general license in subsection (f)(1) ~~of this Section~~, 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 7.4 MBq (200 µCi).

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

C) The general licensee shall use the radioactive material only for the

uses authorized by subsection (f)(1) ~~of this Section~~.

D) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an 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.

E) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in subsection (f)(1)(E) ~~of this Section~~ as required by 32 Ill. Adm. Code 340.1010(a).

4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to subsection (f)(1) ~~of this Section~~:

A) Except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued pursuant to Section 330.280(g) ~~of this Part~~ or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57 or mock iodine-125 to persons generally licensed under subsection (f) ~~of this Section~~ or its equivalent; and

B) Unless one of the following statements, as appropriate, or a statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

~~i)~~ This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, 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 or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer or Importer

~~ii)~~ ~~This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, 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 a Licensing State.~~

~~Name of Manufacturer or Importer~~

5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of subsection (f)(1) ~~of this Section~~ shall report in writing to the Agency, any changes in the information furnished by the licensee in the "Certificate – In Vitro Testing with Radioactive Material Under General License", Agency Form KLM.006. The report shall be furnished within 30 days after the effective date of the change.

6) This general license is subject to the provisions of 32 Ill. Adm. Code 310 and 331.

g) Ice Detection Devices

1) A general license is hereby issued to receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 µCi) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of the device

pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

2) Persons who receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in subsection (g)(1) ~~of this Section~~:

A) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage or contamination and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service those devices; or shall dispose of the device pursuant to the provisions of 32 Ill. Adm. Code 340.1010(a);

B) Shall assure that all labels affixed to the device at the time of receipt, and that bear a statement that prohibits removal of the labels, are maintained on the device; and

C) Are exempt from the requirements of 32 Ill. Adm. Code 340 and 400 except that such persons shall comply with the provisions of 32 Ill. Adm. Code 340.1010(a), 340.1210, 340.1220 and 340.1260.

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

4) This general license is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90 and~~,~~ 341 and Sections 330.310, 330.400 and 330.500 of this Part.

h) Certain Items and Self-Luminous Products Containing Radium-226

1) A general license is hereby issued to any person to acquire, receive, possess, use or transfer, in accordance with the provisions of this subsection (h), radium-226 contained in the following products manufactured prior to November 30, 2007:

A) Antiquities originally intended for use by the general public. For the purposes of this subsection (h)(1)(A), antiquities means products originally intended for use by the general public

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and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts and healing pads;

B) Intact timepieces containing greater than 37 kBq (1 µCi), nonintact timepieces and timepiece hands and dials no longer installed in timepieces;

C) Luminous items installed in air, marine or land vehicles;

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

E) Small radium sources containing no more than 37 kBq (1µCi) of radium-226. For the purposes of this subsection (h)(1)(E), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources such as cloud chambers and spinthariscopes used in educational demonstrations, electron tubes, lightning rods, ionization sources, static eliminators or sources otherwise designated by the Agency.

2) Any person who acquires, receives, possesses, uses or transfers radioactive material under the general license in subsection (h)(1) is exempt from the provisions of 32 Ill. Adm. Code 340 and 400 to the extent that the receipt, possession, use or transfer of radioactive material is within the terms of the general license. This exemption does not apply to any person specifically licensed under this Part.

3) Any person who acquires, receives, possesses, uses or transfers radioactive material in accordance with the general license in subsection (h)(1):

A) Shall notify the Agency within 30 days if there is any indication of possible damage to a product that could result in loss of radioactive material. The report shall provide a brief description of the event and the remedial action taken;

B) Shall not abandon a product containing radium-226. The product and any radioactive material from the product shall only be disposed of in accordance with subsection (h)(3)(D);

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C) Shall not export a product containing radium-226, except in accordance with 10 CFR 110, published at 73 Fed. Reg. 78615, December 23, 2008, exclusive of subsequent amendments or editions; and

D) Shall dispose of a product containing radium-226 only in accordance with 32 Ill. Adm. Code 340.1010(a), or by transfer to a person specifically licensed under this Part to receive the radium-226 in the product, or as otherwise approved by the Agency in writing.

4) The general license in subsection (h)(1) does not authorize the manufacture, assembly, disassembly, repair or import of a product containing radium-226, except that timepieces may be disassembled and repaired.

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(Source: Amended at 35 Ill. Reg. _____, effective _____)

SUBPART C: SPECIFIC AND GENERAL LICENSES

Section 330.240 Filing Applications for Specific Licenses

a) Application requirements:

1) Applications for the issuance, renewal or amendment of specific licenses shall be filed in duplicate and in English.

AGENCY NOTE: Applications involving Agency evaluation of a sealed source or device containing radioactive material shall be in accordance with the requirements of this Section.

2) Applications for initial issuance, amendment and renewal of specific licenses shall be in the format prescribed by the Agency. Each application filed shall be complete with all requested information submitted, including all applicable attachments. The Agency may at any time after the filing of the original application, and before the expiration or termination of the license, require further statements from the applicant or licensee to enable the Agency to determine whether the application should be granted or denied or whether an existing license should be modified or revoked in accordance with Section 330.500~~ of this Part~~.

3) Each application shall include all information required by this Part and any other Parts of 32 Ill. Adm. Code: Chapter II, Subchapters b and d, applicable to the requested authorizations.

4) An application may incorporate by reference information contained in previous applications, statements or reports filed with the Agency, provided such references are clear and specific.

5) Each application and each request for amendment shall be signed by the applicant, licensee, or a person duly authorized in writing to act for and on the licensee or applicant's behalf.

6) Each application shall identify the radiation safety officer. The proposed activities shall be under the same administrative control for radiation safety purposes and the same radiation protection program.

7) An application may request authority to receive, possess, utilize, manufacture, distribute, transfer, own or acquire radioactive material or devices or equipment utilizing or producing radioactive materials. The request can include one or more of these activities.

8) An application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

A) Identify the sealed source or device that contains a sealed source by manufacturer and model as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210, or with an Agreement State or, for a source or device containing naturally occurring or accelerator-produced material, with a state under provisions comparable to 10 CFR 32.210;~~filed in an evaluation sheet in the "Registry of Radioactive Sealed Sources and Devices" maintained by the U.S. Nuclear Regulatory Commission;~~ or

B) Contain the information identified in Section 330.280(m); or~~of this Part.~~

C) Describe, for a sealed source or device containing naturally occurring or accelerator-produced radioactive material

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manufactured prior to November 30, 2007, that is not registered with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 32.210 or with an Agreement State or a former Licensing State and for which the applicant is unable to provide the information described in Section 330.280(m)(2)(B) or (C):

i) The information required by Section 330.280(m)(2) concerning the source and, if applicable, the device; and

ii) Sufficient additional information to demonstrate that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. The information shall 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.

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9) For each location to be listed on the license as an authorized use location, the applicant shall submit:

A) A statement that the applicant owns the facility where radioactive material is used or stored; or

B) A copy of a certified letter sent to the facility owner or authorized representative of the owner informing the owner that radioactive material is being or will be used or stored at the facility; or

C) A copy of a letter or statement from the facility owner or authorized representative of the owner indicating that the owner is aware that radioactive material is being used or will be used or stored at the facility.

AGENCY NOTE: The Radiation Protection Act requires the Agency to provide written notice to a municipality of an application for a new license for a fixed location facility or a license amendment for a new location for a facility.

10) The applicant shall ensure that all applicable fees specified in 32 Ill. Adm. Code 331 are paid in full when due.

11) The applicant shall address the Emergency Plan requirements of Section 330.250(e) ~~of this Part~~, when applicable.

b) Review of application. When evaluating an application or request for amendment, the Agency shall consider:

1) The completeness of the application;

2) The complexity, similarity and proximity of the proposed activities;

3) The radiation protection program proposed by the applicant to ensure the protection of the licensee's personnel, the public and the environment;

4) The qualifications and experience of the applicant's proposed Radiation Safety Officer and authorized users; ~~and~~

5) The applicant's history of compliance; and~~.~~

c) Public access to information. Public inspection of applications and other documents submitted to the Agency pursuant to this Section shall be in accordance with 2 Ill. Adm. Code 1076 and the requirements of the Freedom of Information Act [5 ILCS 140].

(Source: Amended at 35 Ill. Reg. _____, effective _____)

Section 330.260 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Materials

a) Specific Licenses to Medical Institutions for Human Use of Radioactive Material. A specific license allowing a medical institution to use radioactive material for medical diagnosis, medical therapy, or medical research involving humans shall be issued only if the applicant has met the requirements of this Part and 32 Ill. Adm. Code 335.

b) Specific Licenses to Individual Physicians for Human Use of Radioactive Material. An application by an individual physician or group of physicians for a specific license for human use of radioactive material shall be approved only if:

1) The applicant satisfies the general requirements specified in this Part;

2) The application is for use in the applicant's practice in an office outside a medical institution; and

3) The applicant has met the requirements of 32 Ill. Adm. Code 335.

c) Specific Licenses for Distribution or Transfer of Radiopharmaceuticals. In addition to the requirements set forth in this Part, persons licensed by the Agency for manufacture, preparation, or transfer for commercial distribution of radiopharmaceuticals containing radioactive material for medical use under 32 Ill. Adm. Code 335 shall meet the following additional requirements:

1) The applicant satisfies the general requirements specified in Section 330.250 ~~of this Part~~;

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

A) 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);

B) Registered or licensed with a state agency as a drug manufacturer;

C) Licensed as a pharmacy by a state Board of Pharmacy; ~~or~~

D) Operating as a nuclear pharmacy within a Federal medical institution; or

E) A PET drug production facility registered with a state agency;

3) The applicant submits information showing that:

A) The radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act; or

B) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food,

Drug, and Cosmetic Act and the Public Health Service Act;

4) 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;

5) The applicant satisfies the following labeling requirements:

A) 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 shall~~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.

B) 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 shall~~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;

6) A licensee described by subsection (c)(2)(C) or (D)~~ of this Section~~:

A) May prepare radioactive drugs for medical use, as defined in 32 Ill. Adm. Code 335.20, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in subsections (c)(6)(B) and (C)~~ of this Section~~, or an individual under the supervision of an authorized nuclear pharmacist as specified in subsection (c)(15).~~ Actions authorized in this subsection (c)(6)(A) are permitted in spite of more restrictive language in license conditions.~~

B) May allow a pharmacist to work as an authorized nuclear pharmacist if the following conditions ~~of subsections (c)(6)(B)(i) through (iii)~~ are met:~~. Actions authorized in this subsection (c)(6)(A) are permitted in spite of more restrictive language in license conditions.~~

i) The~~This~~ individual qualifies as an authorized nuclear pharmacist as defined in Section 330.20;

ii) The~~This~~ individual meets the requirements specified in subsections (c)(18)(B) and (c)(21), and the licensee has received an approved license amendment identifying the~~this~~ individual as an authorized nuclear pharmacist; or

iii) The~~This~~ individual is designated as an authorized nuclear pharmacist in accordance with subsection (c)(6)(C).

C) May designate a pharmacist (as defined in Section 330.20) as an authorized nuclear pharmacist if:

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

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

D) Prior to allowing the individual to work as an authorized nuclear pharmacist under subsections (c)(6)(B)(i) and (iii), shall~~Shall~~ provide to the Agency a copy of the individual's State of Illinois pharmacist license~~pharmacy licensure prior to allowing, under subsections (c)(6)(B)(i) and (iii), the individual to work as an authorized nuclear pharmacist~~ and:

i) A copy of the~~each~~ individual's certification by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission~~NRC~~ or an

Agreement State as specified in subsection (c)(18)(A) with the written attestation signed by a preceptor as required by subsection (c)(18)(B)(iii); or

ii) U.S. Nuclear Regulatory Commission~~An NRC~~ or Agreement State license listing the individual as an authorized nuclear pharmacist; or

iii) A U.S. Nuclear Regulatory Commission~~NRC~~ master materials licensee permit listing the individual as an authorized nuclear pharmacist; or

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

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

7) 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:

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

B) Check each instrument for constancy and proper operation at the beginning of each day of use;

8) Nothing in this Section relieves the licensee from complying with applicable FDA or~~,~~ other Federal or~~and~~ State requirements governing radioactive drugs;

9) Radiopharmaceuticals dispensed, distributed or transferred for human use shall be either:

A) Repackaged from prepared radiopharmaceuticals that have been approved by the FDA for medical use as defined in 32 Ill. Adm. Code 335.20; or

B) Prepared from generators and reagent kits that have been approved by the FDA for medical use, or are subject to the Illinois Food, Drug and Cosmetic Act [410 ILCS 620] or the Pharmacy Practice Act of 1987 [225 ILCS 85];

10) The licensee shall adhere to the concentration limits and other~~perform radiometric tests for molybdenum breakthrough for the first elute of a molybdenum-99/technetium-99m generator following transfer in accordance with the~~ requirements of 32 Ill. Adm. Code 335.4020;

11) The licensee may distribute in vitro test kits to customers but shall neither remove any package insert nor violate the packaging;

12) The licensee shall report to the Agency, within 10 days after occurrence, any irregularities pertaining to identification, labeling, quality or assay of any radiopharmaceuticals received under the authority of this license;

13) A licensee such as a nuclear pharmacy that is~~For licensees~~ authorized to dispense radiopharmaceuticals ~~(such as nuclear pharmacies), the licensee~~ shall ensure that radiopharmaceuticals are dispensed only under the prescription of a physician who is authorized in a specific license to use the radiopharmaceuticals. The licensee shall maintain a copy of the recipient's radioactive material license and shall verify that the physician is authorized to receive the prescribed radiopharmaceutical prior to transfer;

14) A licensee shall apply for and shall~~must~~ receive a license amendment before it receives, prepares~~,~~ or uses radioactive material for a type of use

that is permitted under this Part~~,~~ but that is not authorized on the licensee's current license issued under this Part;

15) Individuals Under Supervision of an Authorized Nuclear Pharmacist

A) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist who is an authorized user shall:

i) In addition to the requirements in 32 Ill. Adm. Code 400.120, instruct the supervised individual in the preparation of radiopharmaceutical material for medical use~~,~~ as appropriate to that individual's involvement with radioactive material; and

ii) Require the supervised individual to follow the instructions of the supervising authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this Section, and license conditions.

B) A licensee that permits supervised activities under ~~of~~ this subsection (c)(15) is responsible for the acts and omissions of the supervised individual;

16) A licensee shall apply for and shall~~must~~ receive a license amendment identifying an authorized nuclear pharmacist as defined in Section 330.20 of this Part~~, and the invidiual meets the requirements in subsections (c)(18) and (c)(21) or, for an experienced nuclear pharmacist, subsection (c)(20),~~ before it allows the~~this~~ individual to work as an authorized nuclear pharmacist. The individual shall meet the requirements in subsections (c)(18) and (21). An experienced nuclear pharmacist shall meet the requirements in subsection (c)(20);

17) The licensee shall require an individual fulfilling the responsibilities of Radiation Safety Officer at a nuclear pharmacy to be an individual who:

A) Is certified by a specialty board whose certification has been recognized by the Agency, the U.S. Nuclear

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Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ and who meets the requirements in subsections (c)(17)(D) and (E) of this Section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:

i) Hold a bachelor's or graduate degree from an accredited college or university in physical science, ~~or~~ engineering or biological science with a minimum of 20 college credits in physical science;

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

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

B) Has met the requirements of subsections (e)(17)(D) and (E) of this Section and completed a structured educational program consisting of:

i) 200 hours of didactic training in the following areas: radiation physics and instrumentation,~~;~~ radiation protection,~~;~~ mathematics pertaining to the use and measurement of radioactivity,~~;~~ radiation biology and~~,~~ radiation dosimetry;

ii) 1 year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or former Licensing State license or a permit issued

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by ~~a~~the U.S. Nuclear Regulatory Commission master material licensee that authorizes similar types and uses of radioactive material involving shipping, receiving and performing related radiation monitoring;

iii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, instruments used to measure radionuclides and survey meters;

iv) Securing and controlling radioactive material;

v) Using administrative controls to avoid mistakes in the administration of radioactive material;

vi) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

vii) Using emergency procedures to control radioactive material; and

viii) Disposing of radioactive material; or

C) Is an authorized nuclear pharmacist identified on the licensee's license, meets the requirements of subsections (c)(17)(D) and (E) of this Section and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and

D) Obtained~~Has obtained~~ written attestation, signed by a preceptor authorized nuclear pharmacist Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (c)(17)(E) and (c)(17)(A)(i) and (ii) of this Section or subsection (c)(17)(B) or (C) of this Section and has achieved a level of radiation safety knowledge sufficient to function independently as an

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authorized nuclear pharmacist Radiation Safety Officer; and

E) Trained~~Has training~~ in the radiation safety, regulatory issues and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer or authorized nuclear pharmacist, as appropriate, who is authorized for the types of use for which the licensee is seeking approval;

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18) Before a licensee permits an individual~~anyone~~ to work as an authorized nuclear pharmacist under his or her license, ~~except for subsection (c)(19),~~ the licensee shall require the individual~~authorized nuclear pharmacist~~ to be a State of Illinois licensed pharmacist who:

A) Is certified as a nuclear pharmacist by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an~~,~~ Agreement State ~~or Licensing State~~ and who meets the requirements in subsection (c)(18)(B)(iii). To be recognized, a specialty board shall require a candidate~~all candidates~~ for certification to ~~meet the following requirements~~:

i) Graduate~~Has graduated~~ from a pharmacy program accredited by the American Council of Pharmaceutical Education (ACPE) or pass~~have passed~~ the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

ii) Hold a current, active license to practice pharmacy;

iii) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

iv) Pass an examination in nuclear pharmacy, administered by diplomate~~the diplomats~~ of the specialty board, that evaluates~~assessed~~ knowledge and competency in ~~the~~ procurement, compounding, quality assurance, dispensing,

distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes~~,~~ and research and development; or

B) Has completed 700 hours in a structured educational program consisting of both didactic training in radiation physics and instrumentation or radiation protection with:

i) 200 hours of didactic training in radiation physics and instrumentation,~~;~~ radiation protection,~~;~~ mathematics pertaining to the use and measurement of radioactivity,~~;~~ chemistry of radioactive material for medical use and,~~;~~ radiation biology; and

ii) Supervised practical experience in a nuclear pharmacy involving shipping, receiving~~,~~ and performing related radiation surveys; using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters~~,~~ and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides; calculating, assaying~~,~~ and safely preparing dosages for patients or human research subjects; use of administrative controls to avoid medical events in the administration of radioactive~~byproduct~~ material; use of procedures to prevent or minimize radioactive contamination and use of proper decontamination procedures; and

iii) Written~~Has obtained written~~ attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (c)(18)(B) or subsections (c)(18)(A)(i) through (iii) ~~(c)(18)(A)(i) (iii) or (B)~~ and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist;

AGENCY NOTE: The requirements in this subsection (c)(18) do not apply to an individual who meets the requirements of subsection (c)(19).

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19) An individual identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or

former Licensing State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission or~~,~~ Agreement State broad scope licensee or master materials license permit or by a master materials license permittee of broad scope;

20) Training for Experienced Nuclear Pharmacist. A State of Illinois licensed pharmacist who has completed a structured educational program as specified in subsection (c)(18)(B) before October 24, 2007 and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement and recentness of training to qualify as an authorized nuclear pharmacist;

21) Recentness of Training. The training and experience specified in subsection (c)(18) shall~~must~~ have been obtained within the 7 years preceding the date of application or the individual shall~~must~~ have had related continuing education and experience since the required training and experience was completed;

22) Resolution of Conflicting Requirements During Transition Period. If this Part conflicts with the licensee's radiation safety program as identified in its license, this Part shall apply~~,~~ unless the statements, representations, conditions and procedures in the license are more restrictive. However, if the licensee exercises its privilege to amend its license, the portion amended must comply with the requirements of this Part.

23) Licensing the production of PET radioactive drugs for noncommercial distribution within a consortium. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial distribution within its consortium for use under 32 Ill. Adm. Code 335 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall include:

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A) A request for authorization to produce PET radionuclides or evidence of an existing license issued under this Part or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State; and

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B) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in subsection (c)(2); and

C) If the applicant is a nuclear pharmacy:

i) Verification that the applicant satisfies the requirements of this Section that apply to nuclear pharmacies; and

ii) Identification of each individual authorized to prepare the PET radioactive drugs and documentation that each meets the requirements of an authorized nuclear pharmacist; and

D) The information required by subsection (c)(3) for each PET radioactive drug to be noncommercially distributed within the consortium; and

E) Verification that the applicant is in compliance with:

i) Applicable FDA and other Federal and State requirements governing radioactive drugs; and

ii) The labeling requirements of subsection (c)(5) 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; and

iii) The requirements of subsections (c)(7), (12), (13), (14), (17) and (22).

AGENCY NOTE: Subsection (c)(7) contains requirements for measuring the radioactivity of radioactive drugs.

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d) Use of Sealed Sources in Industrial Radiography. A specific license for use of sealed sources in industrial radiography shall be issued only if the applicant has met the requirements of this Part and 32 Ill. Adm. Code 350 and 405.

e) Use of Radioactive Materials in Wireline Service Operations and Subsurface Tracer Studies. A specific license for use of radioactive material in wireline

operations shall be issued only if the applicant has met the requirements of this Part and 32 Ill. Adm. Code 351.

AGENCY NOTE: Specialty boards~~Boards~~ whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ will be posted on ~~the~~ NRC's website~~Web page~~.

(Source: Amended at 35 Ill. Reg. _____, effective _____)

Section 330.270 Special Requirements for Specific Licenses of Broad Scope

This Section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of those licenses.

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

a) The different types of broad scope licenses are:

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

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 Appendix D, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of Appendix D. 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 Column I of Appendix D for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

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 Appendix D, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II of Appendix D. 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 Column II of Appendix D for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

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

1) The applicant satisfies the general requirements specified in Section 330.250;

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

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

A) The establishment of a Radiation Safety Committee composed of such persons as a Radiation Safety Officer, a representative of management and persons trained and experienced in the safe use of radioactive material;

i) The Committee shall meet at least once each calendar quarter.

ii) To establish a quorum and to conduct business, at least one-half of the Committee membership must be in attendance and shall include, at a minimum, the management's representative, an authorized user and the Radiation Safety Officer. However, no more than once per year, the Radiation Safety Officer's designee may substitute

for the Radiation Safety Officer, provided the designee has been given a written report. The report shall include all information necessary for that meeting, such as the minutes of the previous Committee meeting and reports by the Radiation Safety Officer. Reports by the Radiation Safety Officer shall include reports of investigations and information necessary for the reviews. To maintain membership on the Committee, a member must attend at least one-half of the meetings held in any year.

iii) The minutes of each Radiation Safety Committee meeting shall include:

- The date of the meeting;
- Members in attendance;
- Members absent;
- Summary of deliberations and discussions;
- Recommended actions and the results of all votes; and
- Documentation of the radiation protection program review required by 32 Ill. Adm. Code 340.110(c).

iv) The Committee shall provide each member with a copy of the meeting minutes before the next meeting and retain one copy for 5 years from the meeting date.

B) The appointment of a Radiation Safety Officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters.

C) The establishment of appropriate administrative procedures to assure:

i) Control of procurement and use of radioactive material;

ii) Completion of safety evaluations of proposed uses of

radioactive material that 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

iii) Review, approval and recording by the Radiation Safety Committee of safety evaluations of proposed uses prepared in accordance with subsection (b)(3)(C)(ii) prior to use of the radioactive material; and

4) The applicant or its predecessor has been a specific licensee of the Agency for 5 years.

c) An application for a Type B specific license of broad scope will be approved if:

1) The applicant satisfies the general requirements specified in Section 330.250; and

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

A) The nomination of a Radiation Safety Officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

B) The establishment of appropriate administrative procedures to assure:

i) Control of procurement and use of radioactive material;

ii) Completion of safety evaluations of proposed uses of radioactive material that 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

iii) Review, approval and recording by the Radiation Safety Officer of safety evaluations of proposed uses prepared in

accordance with subsection (c)(2)(B)(ii) prior to use of the radioactive material.

d) An application for a Type C specific license of broad scope will be approved if:

1) The applicant satisfies the general requirements specified in Section 330.250;

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

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

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

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

e) Specific licenses of broad scope are subject to the following conditions:

1) Unless specifically authorized, persons licensed pursuant to this Section shall not:

A) Conduct tracer studies in the environment involving direct release of radioactive material;

B) Receive, acquire, own, possess, use or transfer devices containing 3.7 PBq (100 kCi) or more of radioactive material in sealed sources used for irradiation of materials;

C) Conduct activities for which a specific license issued by the

Agency under Section 330.260 or 330.280 is required; or

D) 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) 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.

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 Radiation Safety Officer.

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 the requirements of subsection (d)(2).

(Source: Amended at 35 Ill. Reg. _____, effective _____)

Section 330.280 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material

a) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations

1) In addition to the requirements set forth in Section 330.250, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the radioactive material to persons exempted from this Part pursuant to Section 330.30 or 330.40(a) will be issued if:

A) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is

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

B) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A 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.

2) Each person licensed under this subsection (a) is required to maintain records of transfer of material and shall file a report with the Agency that shall identify the following:

A) Type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

B) 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;

C) The radionuclide, activity and activity assay date of radioactive material introduced into each product or material; and

D) The initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

3) The licensee shall file the report within 30 days after any of the following events:

A) 5 years have passed since~~after filing~~ the preceding report was filed; or

B) The licensee has:~~Filing an application for renewal of the license under Section 330.330; or~~

i) Filed an application for renewal of the license under Section 330.320; or

ii) Notified the Agency under Section 330.325(c) that the licensee has ended activities authorized under the license issued under this subsection (a).

~~C)~~ ~~Notifying the Agency under Section 330.320(b) of the licensee's decision to permanently discontinue activities authorized under the license issued under this subsection (a).~~

4) The report shall cover the period between the filing of the preceding report and an occurrence specified in subsection (a)(3). If no transfers of radioactive material have been made under this subsection (a) during the reporting period, the report shall so indicate.

5) The licensee shall maintain the record of a transfer for a period of 1 year after the event has been included in a report to the Agency.

6) 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 Section 330.30 or 330.40(a) or the equivalent regulations of the U.S. Nuclear Regulatory Commission (10 CFR 30.14) or of an Agreement State, except in accordance with a specific license issued pursuant to this subsection (a).

b) Licensing the Distribution of Radioactive Material in Exempt Quantities

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

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~~1) An application for a specific license to distribute NARM to persons exempted, pursuant to Section 330.40(b) of this Part, will be approved if:~~

~~A) 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;~~

~~B) 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~~

~~C) The applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.~~

~~2) The license issued under subsection (b)(1) of this Section is subject to the following conditions:~~

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

~~B) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Section 330.40(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 microSv (500 microrem) per hour.~~

~~C) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label that:~~

~~i) Identifies the radionuclide and activity; and~~

ii) Bears the words "Radioactive Material".

D) In addition to the labeling information required by subsection (b)(2)(C) of this Section, the label affixed to the immediate container, or an accompanying brochure, shall:

i) State that the contents are exempt from Licensing State requirements;

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

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

3) Each person licensed under this subsection (b) is required to maintain records and file reports as follows:

A) Records of transfer of material identifying, by name and address, each person to whom radioactive material is transferred for use under Section 330.40(b) of this Part or the equivalent regulations of an Agreement State, or a Licensing State and stating the kinds and quantities of radioactive material transferred. The licensee shall maintain the record of a transfer for a period of 1 year after the event is included in a summary report to the Agency.

B) The licensee shall file a summary report stating the total activity of each radioisotope transferred under the specific license with the Agency.

C) The licensee shall file the summary report within 30 days following:

i) 5 years after filing the preceding report; or

~~ii)~~ ~~Filing an application for renewal of the license under Section 330.330 of this Part; or~~

~~iii)~~ ~~Notifying the Agency under Section 330.320(b) of this Part of the licensee's decision to permanently discontinue activities authorized under the license issued under subsection (b) of this Section.~~

~~D)~~ ~~The report shall cover the period between the filing of the preceding report and an occurrence specified in subsection (b)(3)(C) of this Section. If no transfers of radioactive material have been made under subsection (b) of this Section during the reporting period, the report shall so indicate.~~

c) 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 Section 330.40(c)(3) of this Part will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, published January 1, 1993, exclusive of subsequent amendments or editions. The maximum activity of radium-226 in each device shall not exceed 3.7 kBq (100 nCi).~~

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

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d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under Section 330.220(b). ~~of this Part~~

AGENCY NOTE: Subsection (o) describes~~Section 330.280(n) of this Part contains~~ requirements for radioactive material transfer reports and records.

1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Section 330.220(b) ~~of this Part~~ or

equivalent regulations of the U.S. Nuclear Regulatory Commission ~~or,~~ an Agreement State ~~or a Licensing State~~ will be approved if:

A) The applicant satisfies the general requirements of Section 330.250 ~~of this Part~~.

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

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

ii) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in 32 Ill. Adm. Code 340.210(a); and

iii) Under accident conditions such as fire and explosion associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads or lens of eye ..... 150 mSv (15 rem)

Hands and forearms; feet and ankles or localized areas of skin averaged over areas no larger than 1 square centimeter ..... 2 Sv (200 rem)

Other organs ..... 500 mSv (50 rem).

C) Each device bears a durable, legible, clearly visible label or labels approved by the Agency, that contain in a clearly identified and separate statement:

i) Instructions and precautions necessary to assure safe installation, operation and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide this information;

ii) The requirement, or lack of requirement, for testing for leakage or contamination, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by radionuclide, activity and activity assay date; and

iii) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

~~Devices Containing Radioactive Material Other Than Naturally Occurring Radioactive Material~~

The receipt, possession, use and transfer of this device, Model___, Serial No.~~9199~~____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL
Name of Manufacturer or Distributor

AGENCY NOTE: The model, serial number and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

~~Devices Containing Naturally-Occurring Radioactive Material~~

~~The receipt, possession, use and transfer of this device, Model4918____, Serial No. _____are subject to a general license or the equivalent and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.~~

~~CAUTION – RADIOACTIVE MATERIAL~~

~~AGENCY NOTE: The model, serial number and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.~~

D) Each device having a separable source housing that provides the primary shielding for the source also bears on the source housing a durable label displaying the device model and serial number, the radionuclide and activity, the words "Caution – Radioactive Material", the radiation symbol described in 32 Ill. Adm. Code 340.Illustration A and the name of the manufacturer or distributor.

E) Each device meeting the criteria of 10 CFR 31.5(c)(13)(i), published at 73 Fed. Reg. 42673, July 23, 2008, exclusive of subsequent amendments or editions ~~(2005)~~ 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 32 Ill. Adm. Code 340.Illustration A.

2) Except as provided in this subsection (d)(2), the interval between tests for proper operation of the on-off mechanism and indicator, if any, shall not exceed 6 months. The interval between tests for contamination of the device or for leakage of radioactive material from the device or for both shall not exceed 3 months for devices containing sources designed to emit alpha particles and 6 months for all other devices. In the event the applicant desires that the device be required to be tested at intervals longer

than the above, the applicant shall include in the application sufficient information to demonstrate that such longer intervals are justified. The information shall include a description of the performance characteristics of the device or similar devices and of design features that have a significant bearing on the probability or consequences of contamination of the device or 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 or contamination of the device, the Agency will consider information that includes, but is not limited to:

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material; and

J) Operating experience with identical devices or similarly designed and constructed devices.

3) In the event the applicant desires that the general licensee under subsectionSection 330.220(b) ~~of this Part~~, or under equivalent regulations of the U.S. Nuclear Regulatory Commission or~~,~~ 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, or contamination by, radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, the applicant shall include in the application written instructions to be followed by the

general licensee, estimated annual 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 an annual dose in excess of 10 percent of the limits specified in 32 Ill. Adm. Code 340.210(a).

4) A person licensed under this subsection (d) ~~of this Section~~ to distribute devices to generally licensed persons shall provide the information in this subsection (d)(4) ~~of this Section~~ to each person to whom a device is to be transferred for possession and use under the general license in Section 330.220(b) ~~of this Part~~. This information shall be provided before a device is transferred. In the case of a transfer through an intermediate person, the information shall be provided to the intended user prior to transfer to the intermediate person. The required information is:

A) A copy of Section 330.220(b) ~~of this Part~~;

AGENCY NOTE: If certain provisions of Section 330.220(b) ~~of this Part~~ do not apply to a particular device, they may be omitted; e.g., tests for leakage or contamination or proper operation of an on-off mechanism and indicator.

B) A copy of 32 Ill. Adm. Code 310.40, 330.310 and 340.1210, 1220 and 1260;

C) A list of the services that may only be performed by a specific licensee;

D) Information on acceptable disposal options, including estimated costs of disposal; and

E) A statement of the Agency's policy to take escalated enforcement action for improper disposal.

5) A person licensed under this subsection (d) to distribute devices to generally licensed persons shall provide the information in this subsection (d)(5) to each person to whom a device is to be transferred for possession and use under a general license equivalent to Section 330.220(b) ~~of this~~

~~Part~~ in the regulations of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~. This information shall be provided before a device is transferred. In the case of a transfer through an intermediate person, the information shall be provided to the intended user prior to transfer to the intermediate person. The required information is:

A) A copy of the following regulations of the U.S. Nuclear Regulatory Commission, exclusive of subsequent amendments or editions,~~10 CFR 31.5, 31.2, 30.51, 20.2201 and 20.2202 (2005)~~ or the equivalent regulations of an Agreement State ~~or Licensing State~~. The U.S. Nuclear Regulatory Commission regulations are 10 CFR 31.5, published at 73 Fed. Reg. 42673, July 23, 2008, 10 CFR 31.2, published at 65 Fed. Reg. 79187, December 18, 2000, 10 CFR 30.51, published at 61 Fed. Reg. 24673, May 16, 1996, 10 CFR 20.2201, published at 67 Fed. Reg. 3585, January 25, 2002 and 10 CFR 20.2202, published at 63 Fed. Reg. 39483, July 23, 1998. If ~~a copy of~~ the U.S. Nuclear Regulatory Commission~~NRC~~ regulations are~~is~~ provided to a prospective general licensee in lieu of ~~the~~ applicable Agreement State ~~or Licensing State~~ regulations, they~~it~~ shall be accompanied by a note explaining that use of the device is regulated by the Agreement State ~~or Licensing State~~;

AGENCY NOTE: If certain provisions of the regulations do not apply to a particular device, they may be omitted; e.g., tests for leakage or contamination or proper operation of an on-off mechanism and indicator.

B) A list of the services that may only be performed by a specific licensee;

C) Information on acceptable disposal options, including estimated costs of disposal;

D) A statement of the policies of the U.S. Nuclear Regulatory Commission and most Agreement States ~~and Licensing States~~ to take escalated enforcement action for improper disposal; and

E) The name or title, address and phone number of the contact at the U.S. Nuclear Regulatory Commission or~~,~~ Agreement State ~~or~~

~~Licensing State~~ regulatory agency from whom additional information may be obtained.

6) A person licensed under this subsection (d) may propose, for approval by the Agency, an alternative method of informing customers.

7) Each device transferred after February 19, 2002, shall meet the labeling requirements of subsections (d)(1)(C), (D) and (E) of this Section.

8) If a license is to be terminated or if notification of bankruptcy is required by Section~~subsection~~ 330.310(j) ~~of this Section~~, a person licensed under this subsection (d) shall, upon request, provide to the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ the records of final disposition required by subsection (o)(8) of this Section.

e) Special Requirements for the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft

1) An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Section 330.220(c) ~~of this Part~~ will be approved if:

A) The applicant satisfies the general requirements specified in Section 330.250 ~~of this Part~~; and

B) The applicant satisfies the requirements of the following regulations of the U.S. Nuclear Regulatory Commission, exclusive of subsequent amendments or editions,~~10 CFR 32.53 32.55 and 32.101, published January 1, 1993, exclusive of subsequent amendments or editions,~~ or their equivalent. The regulations are 10 CFR 32.53, published at 43 Fed. Reg. 6923, February 17, 1978, 10 CFR 32.54, published at 63 Fed. Reg. 39483, July 23, 1998, 10 CFR 32.55, published at 39 Fed. Reg. 26397, July 19, 1974 and 10 CFR 32.101, published at 30 Fed. Reg. 8192, June 26, 1965.

2) Each person licensed under this subsection (e) shall file an annual report with the Agency that shall state the total activity of tritium or promethium-147 transferred to persons generally licensed under Section 330.220(c) ~~of~~

this Part or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The report shall identify each general licensee by name and address, state the kinds and numbers of luminous devices transferred and specify the activity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter.

f) Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under Section 330.220(e) of this Part. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Section 330.220(e) of this Part will be approved if:

1) The applicant satisfies the general requirements of Section 330.250 of this Part; and

2) The applicant satisfies the requirements of 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, and 10 CFR 70.39, published at 43 Fed. Reg. 6925, February 17, 1978. The applicant shall also certify that itJanuary 1, 1993 and certifies that the applicant will satisfy, and subsequently satisfies, the requirements of 10 CFR 32.58, 32.59 and 32.102, published at 72 Fed. Reg. 55929, October 1, 2007,January 1, 1993, exclusive of subsequent amendments or editions.

g) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of Section 330.220(f) of this Part, or equivalent regulations of the U.S. Nuclear Regulatory Commission or, an Agreement State or a Licensing State, will be approved if:

1) The applicant satisfies the general requirements specified in Section 330.250 of this Part.

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

A) Carbon-14 in units not exceeding 370 kBq (10 µCi) each.

B) Cobalt-57 in units not exceeding 370 kBq (10 µCi) each.

C) Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 µCi) each.

D) Iodine-125 in units not exceeding 370 kBq (10 µCi) each.

E) Mock iodine-125 in units not exceeding 1.85 kBq (50 nCi) of iodine-129 and 185 Bq (5 nCi) of americium-241 each.

F) Iodine-131 in units not exceeding 370 kBq (10 µCi) each.

G) Iron-59 in units not exceeding 740 kBq (20 µCi) each.

H) Selenium-75 in units not exceeding 370 kBq (10 µCi) each.

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

A) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 µCi) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 1.85 MBq (50 µCi) of hydrogen-3 (tritium); 740 kBq (20 µCi) of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (50 nCi) of iodine-129 and 185 Bq (5 nCi) of americium-241 each; and

B) Displaying the radiation caution symbol described in 32 Ill. Adm. Code 340.910(a) and the words, "CAUTION – RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

4) The~~One of the~~ following statement~~statements, as appropriate~~, or a statement that contains the information called for in ~~one of~~ the following statement~~statements~~, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

~~A)~~ This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, 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 or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

~~B)~~ ~~This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, 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 a Licensing State.~~

5) The label affixed to the unit, or the leaflet or brochure that accompanies the package, contains information about the precautions to be followed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the manufacturer shall state in the directions that this item shall be disposed of in compliance with 32 Ill. Adm. Code 340.1010(a) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

h) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Section 330.220(g) ~~of this Part,~~ will be approved if:

1) The applicant satisfies the general requirements of Section 330.250; and

2) The criteria of 10 CFR 32.61, published at 58 Fed. Reg. 67660, December 22, 1993, 32.62, published at 43 Fed. Reg. 6923, February 17, 1978, and 32.103, published at 30 Fed. Reg. 9906, August 10, 1965~~January 1, 1993~~, exclusive of subsequent amendments or editions, are met.

i) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals~~radiopharmeceuticals~~ containing radioactive material for use by persons licensed pursuant to Section 330.260(a), (b) or (c) for the uses described in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010 will be approved if:

1) The applicant satisfies the general requirements specified in Section 330.250 ~~of this Part~~;

2) The applicant submits information showing that:

A) The radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act (21 USC 301)or the Public Health Service Act (42 USC 201 et seq.); or

B) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act;

3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package and shielding provided by the packaging of the radioactive material that~~which~~ is appropriate for safe handling and storage of radiopharmaceuticals by specific licensees; and

4) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, activity and activity assay date and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a), (b) or (c) for radioactive material specified in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~. The labels, leaflets or brochures required by this subsection (i) are in addition to the labeling required by the FDA and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

j) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material

AGENCY NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals

containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have such reagent kits approved by the Agency for use by persons licensed pursuant to Section 330.260(a), (b) or (c) ~~of this Part~~ for generators or reagent kits specified in 32 Ill. Adm. Code 335.4010 may submit the pertinent information specified in this subsection (j).

An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Section 330.260(a), (b) or (c) ~~of this Part~~ for the uses specified in 32 Ill. Adm. Code 335.4010 will be approved if:

1) The applicant satisfies the general requirements specified in Section 330.250 ~~of this Part~~;

2) The applicant submits evidence that:

   A) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act; or

   B) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act;

3) The applicant submits information on the radionuclide, chemical and physical form, packaging, including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

4) The label affixed to the generator or reagent kit contains information on the radionuclide, activity and activity assay date; and

5) The label affixed to the generator or reagent kit, or the leaflet or brochure that accompanies the generator or reagent kit, contains:

   A) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be

used in eluting the generator or processing radioactive material with the reagent kit; and

B) A statement that the generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to Section 330.260(a), (b) or (c) ~~of this Part~~ and 32 Ill. Adm. Code 335.4010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~. The labels, leaflets or brochures required by this subsection (j) are in addition to the labeling required by the FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

k) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Section 330.260(a) or (b) ~~of this Part~~ for use as a calibration, transmission or reference source in 32 Ill. Adm. Code 335.2040 or for the uses listed in 32 Ill. Adm. Code 335.2140, 335.6010, 335.7010 and 335.8010 will be approved if:

1) The applicant satisfies the general requirements in Section 330.250 ~~of this Part~~;

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

A) The radioactive material contained, its chemical and physical form and activity;

B) Details of design and construction of the source or device;

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

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

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

F) Procedures and standards for calibrating sources and devices;

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

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

3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, activity and activity assay date, radiation symbol and/or "Caution Radioactive Material", serial number, model, manufacturer name or logo, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a), ~~or~~ (b) or (c)~~of this Part~~ and 32 Ill. Adm. Code 335.2040, 335.2140, 335.6010, 335.7010 and 335.8010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~, provided that the labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;

4) In the event the applicant desires that the source or device be required to be tested for leakage of, or contamination by, radioactive material at intervals longer than 6 months, the applicant shall include in the application sufficient information to demonstrate that the 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 radioactive contamination or leakage of radioactive material from the source; and

5) In determining the acceptable interval for tests of leakage of, or contamination by, radioactive material, the Agency will consider information that includes, but is not limited to:

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material;

J) Operating experience with identical sources or devices or similarly designed and constructed sources or devices; and

K) Proposed use of source.

l) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Section 330.210(d) ~~of this Part~~ or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

1) The applicant satisfies the general requirements specified in Section 330.250 ~~of this Part~~.

2) The applicant submits sufficient information relating to the design (including blueprints), manufacture (construction materials and methods), prototype testing (description of testing that will be done and the

acceptance criteria), quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to assure that possession, use or transfer of the depleted uranium in the product or device will not cause any individual to receive in any period of 1 year a radiation dose in excess of 10 percent of the limits specified in 32 Ill. Adm. Code 340.210(a).

3) The applicant submits information assuring that the presence of depleted uranium for a mass-volume application in the product or device will provide a unique benefit~~benefits~~ to the public, i.e., a benefit that could not be achieved but for the use of depleted uranium. The applicant's methods for use and handling of the product or device will not result in uncontrolled disposal or dispersal of depleted uranium into the environment.

4) The Agency will deny any application for a specific license under this subsection (l) if the end uses of the industrial product or device cannot be reasonably foreseen.

5) Each person licensed pursuant to this subsection (l) shall:

A) 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;

B) Label or mark each unit to:

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

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

C) 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";

D) Furnish:

i) A copy of the general license contained in Section 330.210(d) ~~of this Part~~ and a copy of the form "Registration Certificate – Use of Depleted Uranium Under General License", to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in Section 330.210(d) ~~of this Part~~; or

ii) A copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Section 330.210(d) ~~of this Part~~ 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 Section 330.210(d) ~~of this Part~~ and a copy of the form "Registration Certificate – Use of Depleted Uranium Under General License", to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in Section 330.210(d) ~~of this Part~~;

E) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in Section 330.210(d) ~~of this Part~~. The~~Such~~ report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred and the activity 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 the~~such a~~ product or device is transferred to the generally licensed person. If no transfers have been made to

persons generally licensed under Section 330.210(d) during the reporting period, the report shall so indicate;

F) File a report that identifies each general licensee by name and address, an individual by name and/or position who constitutes a point of contact between the Agency and the general licensee, the type and model number of the device transferred and the activity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. The licensee shall report:

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

ii) To the responsible state agency all transfers of devices manufactured and distributed pursuant to this subsection (l) for use under a general license in that state's regulations equivalent to Section 330.210(d) ~~of this Part~~;

iii) To the U.S. Nuclear Regulatory Commission if no transfers have been made by the licensees during the reporting period;

iv) To the responsible Agreement State agency upon the request of that agency if no transfers have been made to general licensees within a particular Agreement State during the reporting period; and

G) Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Section 330.210(d) ~~of this Part~~ or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the activity of depleted uranium in each product or device transferred and

compliance with the report requirements of this subsection (l)~~Section~~.

m) Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.

1) An application for license to manufacture, import or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive such sealed sources or devices will be approved subject to the following conditions:

A) The applicant satisfies the general requirements specified in Section 330.250~~ of this Part~~;

B) The licensee subject to this subsection (m) shall not transfer a sealed source or device containing a sealed source to any person except in accordance with the requirements of Section 330.400~~ of this Part~~.

2) Any manufacturer, importer 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 Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices".

A) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in English and in duplicate. The request~~ and~~ shall include information required by subsection (m)(2)(B) or (C)~~ of this Section~~, as applicable, demonstrating that the radiation safety properties of the source or device will not endanger public health and safety or property.

B) A request for evaluation of a sealed source shall include the following radiation safety information:

i) Proposed uses for the sealed source;

ii) Chemical and physical form and maximum quantity of radioactive material in the sealed source;

iii) Details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;

iv) Details of construction of the sealed source, including a description of materials used in construction;

v) Radiation profile of a prototype sealed source;

vi) Procedures for and results of prototype testing;

vii) Details of quality control procedures to be followed in manufacture;

viii) A description or facsimile of labeling to be affixed to the sealed source;

ix) Leak testing procedures; and

x) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the sealed source, as required by Section 330.250 ~~of this Part~~.

C) A request for evaluation of a device containing a sealed source shall include the following radiation safety information:

i) Proposed uses for the device;

ii) Manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;

iii) Details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;

iv) Details of construction of the sealed source, including a description of materials used in construction;

v) Radiation profile of a prototype device;

vi) Procedures for and results of prototype testing;

vii) Details of quality control procedures to be followed in manufacture;

viii) A description or facsimile of labeling to be affixed to the device;

ix) Leak testing procedures;

x) A description of potential hazards in installation, service, maintenance, handling, use and operation of the device;

xi) Information about installation, service and maintenance procedures;

xii) Handling, operating and safety instructions; and

xiii) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device as required by Section 330.250 ~~of this Part~~.

D) When evaluating a sealed source or device, the Agency will apply the radiation safety criteria described in 10 CFR 32.210(d), published at 73 Fed. Reg. 5719, January 31, 2008~~January 1, 1993~~, exclusive of subsequent amendments or editions.

E) The person submitting a request for evaluation of a product shall manufacture and distribute the product in accordance with:

i) The statements and representations, including the quality control program, described in the request; and

ii) The provisions of the evaluation sheet prepared by the Agency and submitted to the ~~U.S. Department of Health and Human Services for filing in the "Radioactive Material~~

~~Reference Manual", or to the~~ U.S. Nuclear Regulatory Commission for filing in the "Registry of Radioactive Sealed Sources and Devices".

n) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. A specific license authorizing the distribution of radioactive materials for diagnostic medical use by a physician under a general license shall be issued only if the applicant for the specific license satisfies the requirements of Section 330.250 ~~of this Part~~ and:

1) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with an approval by the commissioner of Food and Drugs, U.S. Food and Drug Administration, or in accordance with an approval for a biologic product issued by the Secretary, U.S. Department of Health and Human Services; and

2) The~~One of the~~ following statement~~statements, as appropriate~~, or a statement that~~statement which~~ contains the information called for in ~~one of~~ the following statement~~statements~~, appears on the label affixed to the container or appears in the leaflet or brochure that accompanies the package:

~~A)~~ This radiopharmaceutical 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 its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

~~B) This radiopharmaceutical 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 its equivalent of a Licensing State.~~

o) Material Transfer Reports and Records
Each person licensed under subsection (d) ~~of this Section~~ to distribute devices to generally licensed persons shall comply with the requirements of this subsection (o)~~subsection (n) of this Section~~.

1) The person shall report:

   A) To the Agency and to the responsible regulatory agency all transfers of devices to persons for use under the general license in Section 330.220(b) ~~of this Part~~ or the equivalent regulations of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~;

   B) To the Agency and to the responsible regulatory agency all receipts of devices from persons generally licensed under Section 330.220(b) ~~of this Part~~ or the equivalent regulations of the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~;

   C) To the Agency if no transfers were made to or from general licensees during the reporting period; and

   D) To the responsible regulatory agency upon the request of the agency if no transfers during the reporting period were made to or from general licensees in the agency's area of jurisdiction.

2) The report shall be on NRC Form 653, "Transfers of Industrial Devices Report" or in a clear and legible format containing all of the information required by the form. The report shall cover each calendar quarter, shall be filed within 30 days after the end of the calendar quarter and shall clearly indicate the period covered.

3) For a transfer to a general licensee, the report shall provide:

   A) The identity of the 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;

   B) The name, title~~,~~ and phone number of the individual identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

C) The date of transfer;

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

E) The radionuclide and activity contained in the device.

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

5) For a device received from a general licensee, the report shall provide the name and address of the general licensee and the type, model and serial number of the device and the date of receipt. For a device not initially transferred by the reporting person, the report shall provide the name of the manufacturer or distributor.

6) If the person makes a change to a device possessed by a general licensee that necessitates a change in the label, the report shall identify the general licensee, the device and the changes to information on the device label.

7) The report shall clearly identify the person licensed under subsection (d) ~~of this Section~~ that is furnishing the report and shall include the person's specific license number.

8) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this subsection (o). These records shall be maintained for 5 years following the recorded event.

(Source: Amended at 35 Ill. Reg. _____, effective _____)

Section 330.320 Renewal Requirements for Specific Licenses

a) Each licensee issued a specific license shall maintain a valid specific license until the licensee completes the license termination requirements of Section 330.325 ~~of this Part~~ and the Agency has notified the licensee in writing that the specific license is terminated. Each specific license and any amendment to the license issued by the Agency contains an expiration date. Unless the specific license has

been terminated in accordance with Section 330.325~~ of this Part~~, the licensee shall, 30 days prior to the expiration date of the license, file with the Agency:

1) A complete application, in proper format, for license renewal as provided in Section 330.240~~ of this Part~~; or

2) A complete application, in proper format, for a license authorizing, at a minimum, continued possession and storage of any radioactive materials possessed under the expiring specific license.

b) In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license shall not expire until final action has been taken by the Agency.~~ files an application in accordance with subsection (a) of this Section before the expiration date of the specific license, the existing license shall not be terminated until the Agency renews the license or denies the application. An Agency denial of an application can be appealed pursuant to the procedures in 32 Ill. Adm. Code 200.~~

AGENCY NOTE: Nothing in this subsection (b) is intended to limit the Agency's authority, if circumstances warrant, to take emergency action in accordance with the Act [420 ILCS 40], or other appropriate action in regard to a specific license in accordance with procedures in 32 Ill. Adm. Code 200.

c) A licensee who fails to comply with the requirements of subsection (a)~~ of this Section~~ shall be subject to such civil penalties and sanctions as may be appropriate to the circumstances, in accordance with the Radiation Protection Act and 32 Ill. Adm. Code 310. In addition, if the expiration date passes without license termination requirements having been met by the licensee and without a timely renewal application having been filed by the licensee before the expiration date, the authority of the licensee to engage in licensed activities as specified in the specific license shall expire at the end of the specified expiration date. The passing of the expiration date shall not relieve the licensee of the duties and responsibilities of applying for and maintaining a valid specific license, decommissioning, reclaiming, and meeting the license termination requirements of Section 330.325~~ of this Part~~. Immediately upon the passing of the expiration date, a licensee that has neither met license termination requirements nor filed a timely application under subsection (a)~~ of this Section~~ shall:

1) Cease use of radioactive material;

2) Store all radioactive material in a secure location and limit activities involving radioactive material to those necessary for shipping, transferring and disposing of the radioactive material;

3) File either a new application for a specific license or provide information equivalent to that required on Agency Form KLM.007 (Certificate Termination and Disposition or Radioactive Material);

4) Comply with all applicable Agency regulations;

5) Comply with the license conditions of the expired license until either a new license is issued or the termination requirements of Section 330.325 ~~of this Part~~ are met; and

6) Comply with any orders issued by the Agency in accordance with the Act and 32 Ill. Adm. Code 200 that result from violation of subsection (a) ~~of this Section~~ or any other applicable provisions of Agency regulations or the Act.

(Source: Amended at 35 Ill. Reg. _____, effective _____)

Section 330.330 Renewal of Licenses (Repealed)

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~~a) Applications for renewal of specific licenses shall be filed in accordance with Section 330.240 of this Part.~~

~~b) In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license shall not expire until final action has been taken by the Agency.~~

(Source: Repealed at 35 Ill. Reg. _____, effective _____)

Section 330.400 Transfer of Material

a) No licensee shall transfer radioactive material except as authorized pursuant to this Section.

b) Except as otherwise provided in his license and subject to the provisions of subsections (c) and (d), any licensee may transfer radioactive material:

1) To the Agency if prior approval has been granted by the Agency;

2) To the U.S. Department of Energy;

3) To any person exempt from the regulations in this Part to the extent permitted under the~~such~~ exemption;

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

5) As otherwise authorized by the Agency in writing.

c) Before transferring radioactive material to a specific licensee of the Agency, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ 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 radionuclide, form and activity of radioactive material to be transferred.

d) The following methods for the verification required by subsection (c) are acceptable:

1) The transferor may possess a current copy of the transferee's specific license or registration certificate authorizing the transferee to receive the radionuclide, form and activity of radioactive material to be transferred;

2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the radionuclide, form and activity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the radionuclide, form and activity 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 10 days;

4) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ regarding the identity of licensees and the scope and expiration dates of licenses and registration; or

5) When none of the methods of verification described in subsections (d)(1) through (4) are readily available or when a transferor desires to verify that information received by one of the~~such~~ methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or a Licensing State~~ that the transferee is licensed to receive the radioactive material.

e) Shipment and transport of radioactive material shall be in accordance with the provisions of 32 Ill. Adm. Code 341.

(Source: Amended at 35 Ill. Reg. _____, effective _____)

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Section 330.APPENDIX A Exempt Concentrations

Element (atomic number)	Isotope	Column I Gas Concentration[1] Bg/ml	Column I Gas Concentration[1] microCi/ml	Column II Liquid and Solid Concentration[2] Bg/ml	Column II Liquid and Solid Concentration[2] microCi/ml
Antimony (51)	Sb-122			1.11×10^{1}	3×10^{-4}
	Sb-124			7.40×10^{0}	2×10^{-4}
	Sb-125			3.70×10^{1}	1×10^{-3}
Argon (18)	Ar-37	3.70×10^{1}	1×10^{-3}		
	Ar-41	1.48×10^{-2}	4×10^{-7}		
Arsenic (33)	As-73			1.85×10^{2}	5×10^{-3}
	As-74			1.85×10^{1}	5×10^{-4}
	As-76			7.40×10^{0}	2×10^{-4}
	As-77			2.96×10^{1}	8×10^{-4}
Barium (56)	Ba-131			7.40×10^{1}	2×10^{-3}
	Ba-140			1.11×10^{1}	3×10^{-4}
Beryllium (4)	Be-7			7.40×10^{2}	2×10^{-2}
Bismuth (83)	Bi-206			1.48×10^{1}	4×10^{-4}
Bromine (35)	Br-82	1.48×10^{-2}	4×10^{-7}	1.11×10^{2}	3×10^{-3}
Cadmium (48)	Cd-109			7.40×10^{1}	2×10^{-3}
	Cd-115m			1.11×10^{1}	3×10^{-4}
	Cd-115			1.11×10^{1}	3×10^{-4}
Calcium (20)	Ca-45			3.33×10^{0}	9×10^{-5}
	Ca-47			1.85×10^{1}	5×10^{-4}
Carbon (6)	C-14	3.70×10^{-2}	1×10^{-6}	2.96×10^{2}	8×10^{-3}
Cerium (58)	Ce-141			3.33×10^{1}	9×10^{-4}
	Ce-143			1.48×10^{1}	4×10^{-4}
	Ce-144			3.70×10^{0}	1×10^{-4}
Cesium (55)	Cs-131			7.40×10^{2}	2×10^{-2}
	Cs-134m			2.22×10^{3}	6×10^{-2}
	Cs-134			3.3×10^{0}	9×10^{-5}
Chlorine (17)	Cl-38	3.33×10^{-2}	9×10^{-7}	1.48×10^{2}	4×10^{-3}
Chromium (24)	Cr-51			7.40×10^{2}	2×10^{-2}

Cobalt (27)	Co-57	$1.85x10^{2}$	$5x10^{-3}$
	Co-58	$3.70x10^{1}$	$1x10^{-3}$
	Co-60	$1.85x10^{1}$	$5x10^{-4}$
Copper (29)	Cu-64	$1.11x10^{2}$	$3x10^{-3}$

Element (atomic number)	Isotope	Column I Gas Concentration[1] Bg/ml	Column I Gas Concentration[1] microCi/ml	Column II Liquid and Solid Concentration[2] Bg/ml	Column II Liquid and Solid Concentration[2] microCi/ml
Dysprosium (66)	Dy-165			$1.48x10^{2}$	$4x10^{-3}$
	Dy-166			$1.48x10^{1}$	$4x10^{-4}$
Erbium (68)	Er-169			$3.33x10^{1}$	$9x10^{-4}$
	Er-171			$3.70x10^{1}$	$1x10^{-3}$
Europium (63)	Eu-152 (9.2h)			$2.22x10^{1}$	$6x10^{-4}$
	Eu-155			$7.40x10^{1}$	$2x10^{-3}$
Fluorine (9)	F-18	$7.40x10^{-2}$	$2x10^{-6}$	$2.96x10^{2}$	$8x10^{-3}$
Gadolinium (64)	Gd-153			$7.40x10^{1}$	$2x10^{-3}$
	Gd-159			$2.96x10^{1}$	$8x10^{-4}$
Gallium (31)	Ga-72			$1.48x10^{1}$	$4x10^{-4}$
Germanium (32)	Ge-71			$7.40x10^{2}$	$2x10^{-2}$
Gold (79)	Au-196			$7.40x10^{1}$	$2x10^{-3}$
	Au-198			$1.85x10^{1}$	$5x10^{-4}$
	Au-199			$7.40x10^{1}$	$2x10^{-3}$
Hafnium (72)	Hf-181			$2.59x10^{1}$	$7x10^{-4}$
Hydrogen (1)	H-3	$1.85x10^{-1}$	$5x10^{-6}$	$1.11x10^{3}$	$3x10^{-2}$
Indium (49)	In-113m			$3.70x10^{2}$	$1x10^{-2}$
	In-114m			$7.40x10^{0}$	$2x10^{-4}$
Iodine (53)	I-126	$1.11x10^{-4}$	$3x10^{-9}$	$7.40x10^{-1}$	$2x10^{-5}$
	I-131	$1.11x10^{-4}$	$3x10^{-9}$	$7.40x10^{-1}$	$2x10^{-5}$
	I-132	$2.96x10^{-3}$	$8x10^{-8}$	$2.22x10^{1}$	$6x10^{-4}$
	I-133	$3.70x10^{-4}$	$1x10^{-8}$	$2.59x10^{0}$	$7x10^{-5}$
	I-134	$7.40x10^{-3}$	$2x10^{-7}$	$3.70x10^{1}$	$1x10^{-3}$
Iridium (77)	Ir-190			$7.40x10^{1}$	2x10-3
	Ir-192			$1.48x10^{1}$	$4x10^{-4}$
	Ir-194			$1.11x10^{1}$	$3x10^{-4}$
Iron (26)	Fe-55			$2.96x10^{2}$	$8x10^{-3}$
	Fe-59			$2.22x10^{1}$	$6x10^{-4}$

Krypton (36)	Kr-85m	3.70×10^{-2}	1×10^{-6}		
	Kr-85	1.11×10^{-1}	3×10^{-6}		
Lanthanum (57)	La-140			7.40×10^{0}	2×10^{-4}
Lead (82)	Pb-203			1.48×10^{2}	4×10^{-3}

Element (atomic number)	Isotope	Column I Gas Concentration[1] Bg/ml	Column I Gas Concentration[1] microCi/ml	Column II Liquid and Solid Concentration[2] Bg/ml	Column II Liquid and Solid Concentration[2] microCi/ml
Lutetium (71)	Lu-177			$3.70x10^{1}$	$1x10^{-3}$
Manganese (25)	Mn-52			$1.11x10^{1}$	$3x10^{-4}$
	Mn-54			$3.70x10^{1}$	$1x10^{-3}$
	Mn-56			$3.70x10^{1}$	$1x10^{-3}$
Mercury (80)	Hg-197m			$7.40x10^{1}$	$2x10^{-3}$
	Hg-197			$1.11x10^{2}$	$3x10^{-3}$
	Hg-203			$7.40x10^{0}$	$2x10^{-4}$
Molybdenum (42)	Mo-99			$7.40x10^{1}$	$2x10^{-3}$
Neodymium (60)	Nd-147			$2.22x10^{1}$	$6x10^{-4}$
	Nd-149			$1.11x10^{2}$	$3x10^{-3}$
Nickel (28)	Ni-65			$3.70x10^{1}$	$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95			$3.70x10^{1}$	$1x10^{-3}$
	Nb-97			$3.33x10^{2}$	$9x10^{-3}$
Osmium (76)	Os-185			$2.59x10^{1}$	$7x10^{-4}$
	Os-191m			$1.11x10^{3}$	$3x10^{-2}$
	Os-191			$7.40x10^{1}$	$2x10^{-3}$
	Os-193			$2.22x10^{1}$	$6x10^{-4}$
Palladium (46)	Pd-103			$1.11x10^{2}$	$3x10^{-3}$
	Pd-109			$3.33x10^{1}$	$9x10^{-4}$
Phosphorus (15)	P-32			$7.40x10^{0}$	$2x10^{-4}$
Platinum (78)	Pt-191			$3.70x10^{1}$	$1x10^{-3}$
	Pt-193m			$3.70x10^{2}$	$1x10^{-2}$
	Pt-197m			$3.70x10^{2}$	$1x10^{-2}$
	Pt-197			$3.70x10^{1}$	$1x10^{-3}$
Potassium (19)	K-42			$1.11x10^{2}$	$3x10^{-3}$
Praseodymium (59)	Pr-142			$1.11x10^{1}$	$3x10^{-4}$
	Pr-143			$1.85x10^{1}$	$5x10^{-4}$
Promethium (61)	Pm-147			$7.40x10^{1}$	$2x10^{-3}$

	Pm-149	1.48×10^{1}	4×10^{-4}
Rhenium (75)	Re-183	2.22×10^{2}	6×10^{-3}
	Re-186	3.33×10^{1}	9×10^{-4}
	Re-188	2.22×10^{1}	1×10^{-4}
Rhodium (45)	Rh-103m	3.70×10^{3}	1×10^{-1}
	Rh-105	3.70×10^{1}	1×10^{-3}

Element (atomic number)	Isotope	Column I Gas Concentration[1] Bg/ml	Column I Gas Concentration[1] microCi/ml	Column II Liquid and Solid Concentration[2] Bg/ml	Column II Liquid and Solid Concentration[2] microCi/ml
Rubidium (37)	Rb-86			$2.59x10^{1}$	$7x10^{-4}$
Ruthenium (44)	Ru-97			$1.48x10^{2}$	$4x10^{-3}$
	Ru-103			$2.96x10^{1}$	$8x10^{-4}$
	Ru-105			$3.70x10^{1}$	$1x10^{-3}$
	Ru-106			$3.70x10^{0}$	$1x10^{-4}$
Samarium (62)	Sm-153			$2.96x10^{1}$	$8x10^{-4}$
Scandium (21)	Sc-46			$1.48x10^{1}$	$4x10^{-4}$
	Sc-47			$3.33x10^{1}$	$9x10^{-4}$
	Sc-48			$1.11x10^{1}$	$3x10^{-4}$
Selenium (34)	Se-75			$1.11x10^{2}$	$3x10^{-3}$
Silicon (14)	Si-31			$3.33x10^{2}$	$9x10^{-3}$
Silver (47)	Ag-105			$3.70x10^{1}$	$1x10^{-3}$
	Ag-110m			$1.11x10^{1}$	$3x10^{-4}$
	Ag-111			$1.48x10^{1}$	$4x10^{-4}$
Sodium (11)	Na-24			$7.40x10^{1}$	$2x10^{-3}$
Strontium (38)	Sr-85			$3.70x10^{1}$	$1x10^{-3}$
	Sr-89			$3.70x10^{0}$	$1x10^{-4}$
	Sr-91			$2.59x10^{1}$	$7x10^{-4}$
	Sr-92			$2.59x10^{1}$	$7x10^{-4}$
Sulfur (16)	S-35			$2.22x10^{1}$	$6x10^{-4}$
Tantalum (73)	Ta-182			$1.48x10^{1}$	$4x10^{-4}$
Technetium (43)	Tc-96m			$3.70x10^{3}$	$1x10^{-1}$
	Tc-96			$3.70x10^{1}$	$1x10^{-3}$
Tellurium (52)	Te-125m			$7.40x10^{1}$	$2x10^{-3}$
	Te-127m			$2.22x10^{1}$	$6x10^{-4}$
	Te-127			$1.11x10^{2}$	$3x10^{-3}$
	Te-129m			$1.11x10^{1}$	$3x10^{-4}$
	Te-131m			$2.22x10^{1}$	$6x10^{-4}$
	Te-132			$1.11x10^{1}$	$3x10^{-4}$
Terbium (65)	Tb-160			$1.48x10^{1}$	$4x10^{-4}$

Thallium (81)	Tl-200	$1.48x10^{1}$	$4x10^{-3}$
	Tl-201	$1.11x10^{2}$	$3x10^{-3}$
	Tl-202	$3.70x10^{1}$	$1x10^{-3}$
	Tl-204	$3.70x10^{1}$	$1x10^{-3}$

Element (atomic number)	Isotope	Column I Gas Concentration[1] Bg/ml	Column I Gas Concentration[1] microCi/ml	Column II Liquid and Solid Concentration[2] Bg/ml	Column II Liquid and Solid Concentration[2] microCi/ml
Thulium (69)	Tm-170			1.85×10^{1}	5×10^{-4}
	Tm-171			1.85×10^{2}	5×10^{-3}
Tin (50)	Sn-113			3.33×10^{1}	9×10^{-4}
	Sn-125			7.40×10^{0}	2×10^{-4}
Tungsten (Wolfram) (74)	W-181			1.48×10^{2}	4×10^{-3}
	W-187			2.59×10^{1}	7×10^{-4}
Vanadium (23)	V-48			1.11×10^{1}	3×10^{-4}
Xenon (54)	Xe-131m	1.48×10^{-1}	4×10^{-6}		
	Xe-133	1.11×10^{-1}	3×10^{-6}		
	X3-135	3.70×10^{-2}	1×10^{-6}		
Ytterbium (70)	Yb-175			3.70×10^{1}	1×10^{-3}
Yttrium (39)	Y-90			7.40×10^{0}	2×10^{-4}
	Y-91m			1.11×10^{3}	3×10^{-2}
	Y-91			1.11×10^{1}	3×10^{-4}
	Y-92			2.22×10^{1}	6×10^{-4}
	Y-93			1.11×10^{1}	3×10^{-4}
Zinc (30)	Zn-65			3.70×10^{1}	1×10^{-3}
	Zn-69m			2.59×10^{1}	7×10^{-4}
	Zn-69			7.40×10^{2}	2×10^{-2}
Zirconium (40)	Zr-95			2.22×10^{1}	6×10^{-4}
	Zr-97			7.40×10^{0}	2×10^{-4}
Beta-and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		3.70×10^{-6}	1×10^{-10}	3.70×10^{2}	1×10^{-6}

[1] Values are given in Column I only for those materials normally used as gases.

[2] Bq or microCi/g for solids.

NOTE 1: Many radionuclides~~radioisotopes~~ transform into nuclides that~~isotopes which~~ are also radioactive. In expressing the concentrations in this Appendix, the activity stated is that of the parent radionuclide~~isotope~~ and takes into account the daughters.

NOTE 2: For purposes of Section 330.40 where there is involved a combination of radionuclides~~isotopes~~, the limit for the combination should be derived as follows: Determine for each radionuclide~~isotope~~ in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in this Appendix for the radionuclide~~specific isotope~~ when not in combination. The sum of such ratios may not exceed "1".

EXAMPLE:

$$\frac{\text{Concentration of Nuclide~~Isotope~~ A in Product}}{\text{Exempt Concentration of Nuclide~~Isotope~~ A}} + \frac{\text{Concentration of Nuclide~~Isotope~~ B in Product}}{\text{Exempt Concentration of Nuclide~~Isotope~~ B}} \leq 1$$

(Source: Amended at 35 Ill. Reg. _____, effective _____)

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Section 330.APPENDIX C Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

Radioactive Material[1]	Release Fraction	Quantity (GBq)	Quantity (Ci)
Actinium-228	0.001	148,000	4,000
Americium-241	0.001	74	2
Americium-242	0.001	74	2
Americium-243	0.001	74	2
Antimony-124	0.01	148,000	4,000
Antimony-126	0.01	222,000	6,000
Barium-133	0.01	370,000	10,000
Barium-140	0.01	1,110,000	30,000
Bismuth-207	0.01	185,000	5,000
Bismuth-210	0.01	22,200	600
Cadmium-109	0.01	37,000	1,000
Cadmium-113	0.01	2,960	80
Calcium-45	0.01	740,000	20,000
Californium-252	0.001	333	9 (20mg)
Carbon-14 (Non-CO_2)	0.01	1,850,000	50,000
Cerium-141	0.01	370,000	10,000
Cerium-144	0.01	11,100	300
Cesium-134	0.01	74,000	2,000
Cesium-137	0.01	111,000	3,000
Chlorine-36	0.5	3,700	100
Chromium-51	0.01	11,100,000	300,000
Cobalt-60	0.001	185,000	5,000
Copper-64	0.01	7,400,000	200,000
Curium-242	0.001	2,220	60
Curium-243	0.001	110	3
Curium-244	0.001	148	4
Curium-245	0.001	74	2
Europium-152	0.01	18,500	500
Europium-154	0.01	14,800	400
Europium-155	0.01	111,000	3,000
Gadolinium-153	0.01	185,000	5,000
Germanium-68	0.01	74,000	2,000
Gold-198	0.01	1,110,000	30,000
Hafnium-172	0.01	14,800	400

Hafnium-181	0.01	259,000	7,000
Holmium-166m	0.01	3,700	100
Hydrogen-3	0.5	740,000	20,000
Indium-114m	0.01	37,000	1,000
Iodine-125	0.5	370	10
Iodine-131	0.5	370	10
Iridium-192	0.001	1,480,000	40,000
Iron-55	0.01	1,480,000	40,000
Iron-59	0.01	259,000	7,000
Krypton-85	1.0	222,000,000	6,000,000
Lead-210	0.01	296	8
Manganese-56	0.01	2,220,000	60,000
Mercury-203	0.01	370,000	10,000
Molybdenum-99	0.01	1,110,000	30,000
Neptunium-237	0.001	74	2
Nickel-63	0.01	740,000	20,000
Niobium-94	0.01	11,100	300
Phosphorus-32	0.5	3,700	100
Phosphorus-33	0.5	37,000	1,000
Polonium-210	0.01	370	10
Potassium-42	0.01	333,000	9,000
Promethium-145	0.01	148,000	4,000
Promethium-147	0.01	148,000	4,000
Radium-226	0.001	3,700	100
Ruthenium-106	0.01	7,400	200
Samarium-151	0.01	148,000	4,000
Scandium-46	0.01	111,000	3,000
Selenium-75	0.01	370,000	10,000
Silver-110m	0.01	37,000	1,000
Sodium-22	0.01	333,000	9,000
Sodium-24	0.01	370,000	10,000
Strontium-89	0.01	111,000	3,000
Strontium-90	0.01	3,330	90
Sulfur-35	0.5	33,300	900
Technetium-99	0.01	370,000	10,000
Technetium-99m	0.01	14,800,000	400,000
Tellurium-127m	0.01	185,000	5,000
Tellurium-129m	0.01	185,000	5,000
Terbium-160	0.01	148,000	4,000
Thulium-170	0.01	148,000	4,000

Tin-113	0.01	370,000	10,000
Tin-123	0.01	111,000	3,000
Tin-126	0.01	37,000	1,000
Titanium-44	0.01	3,700	100
Vanadium-48	0.01	259,000	7,000
Xenon-133	1.0	33,300,000	900,000
Yttrium-91	0.01	74,000	2,000
Zinc-65	0.01	185,000	5,000
Zirconium-93	0.01	14,800	400
Zirconium-95	0.01	185,000	5,000
Any other beta-gamma emitter	0.01	370,000	10,000
Mixed fission products	0.01	37,000	1,000
Mixed corrosion products	0.01	370,000	10,000
Contaminated equipment, beta-gamma	0.001	370,000	10,000
Irradiated material, any form other than solid noncombustible	0.01	37,000	1,000
Irradiated material, solid noncombustible	0.001	370,000	10,000
Mixed radioactive waste,[2] beta-gamma	0.01	37,000	1,000
Packaged mixed waste, [2] beta-gamma	0.001	370,000	10,000
Any other alpha emitter	0.001	74	2
Contaminated equipment, Alpha	0.0001	740	20
Packaged waste, alpha[2]	0.0001	740	20

[1] For combinations of radioactive materials, the licensee is required to consider whether an emergency plan is needed if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material above exceeds one.

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

(Source: Amended at 35 Ill. Reg. _____, effective _____)