ILLINOIS EMERGENCY MANAGEMENT AGENCY

JB Pritzker
Governor

Alicia Tate-Nadeau
Acting Director

CERTIFICATE OF ADOPTED AMENDMENTS

The Illinois Emergency Management Agency certifies that the attached hereto is a true and correct copy of:

Heading of the Part: Licensing of Radioactive Material

Code Citation: 32 Ill. Adm. Code 330

Sections Involved:

330.20
330.220
330.240
330.260
330.270
330.280
330.310
330.340
330.900
330.APPENDIX D

Statutory Authority: Implementing and authorized by Section 10 and 11 of the Radiation Protection Act of 1990 [420 ILCS 40].

which was duly amended by this Agency.

Signature of Officer

RULES COORDINATOR
Title of Officer

EFFECTIVE DATE
DEC 21 2021

RECEIVED
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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

SUBPART D: TRANSPORTATION

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. 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. 2931, effective February 7, 2011; amended at 35 Ill. Reg. 3969, effective February 28, 2011; emergency amendment at 35 Ill. Reg. 5654, effective March 21, 2011, for a maximum of 150 days; amended at 35 Ill. Reg. 9009, effective June 2, 2011; amended at 37 Ill. Reg. 5789, effective April 16, 2013; amended at 37 Ill. Reg. 7960, effective May 31, 2013; amended at 38 Ill. Reg. 21451, effective October 31, 2014; amended at 39 Ill. Reg.11905, effective August 17, 2015; amended at 39 Ill. Reg. 15706, effective November 24, 2015; amended at 40 Ill. Reg. 12971, effective August 25, 2016; amended at 46 Ill. Reg. 866, effective DEC 21 2021.

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Section 330.20 Definitions

"Associate Radiation Safety Officer" means an individual, who for this Part only:

Meets the requirements in Sections 330.260(c)(17) and (c)(21); and

Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on a specific license that authorizes medical use or the practice of nuclear pharmacy issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; or a permit that authorizes medical use or the practice of nuclear pharmacy issued by a U.S. Nuclear Regulatory Commission master material licensee.

"Authorized nuclear pharmacist" means a pharmacist who:

Meets the requirements in Section 330.260(c)(18), (19) and (21); 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).

"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.

"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.

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

"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 46 Ill. Reg. 866, effective DEC 21 2021)

Section 330.220 General Licenses – Radioactive Material Other Than Source Material

a) 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 (a)(2) through (9), 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 (a)(1) 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) 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 NRC, an Agreement State or a former Licensing State. The devices shall have been received from a specific licensee described in this subsection (a)(2) or through a transfer made under subsection (a)(3)(L).

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 (a)(1):

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 μCi) of other beta and/or gamma emitting material or 370 kBq (10 μCi) 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 the tests required by subsection (a)(3)(B) and other testing, 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, NRC or an Agreement State to perform such activities;

D) Shall maintain records showing compliance with the requirements of subsections (a)(3)(B), (C), (H) and, as applicable, (a)(6)(B). 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 (a)(1) 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 (a)(3)(B) shall be retained for 5 years after the next required test is performed or until the device is transferred or disposed of; and

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

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

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

iv) A record of a quarterly physical inventory, performed for those devices in storage and not in use in accordance with subsection (a)(6)(B), shall be retained for 5 years after the next required test is performed or until the device is transferred or disposed of;

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 nCi) 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, NRC or an Agreement 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 nCi) 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 nCi) 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, 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 (a)(3)(G);

ii) By transfer to another general licensee as provided by subsection (a)(3)(L);

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) or an equivalent specific license issued by NRC or an Agreement State;

iv) By transfer to a person authorized to perform waste collection by a specific license issued by the Agency, NRC or an Agreement State; or

v) As approved under subsection (a)(3)(K);

I) Shall furnish a written report to the Agency within 30 days after transferring or disposing of the device containing radioactive material. The 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) The date of the transfer;

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

J) Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information to the Agency, by an appropriate method listed in 32 Ill. Adm. Code 310.110.;

K) Shall obtain written approval from the Agency before transferring the device to any other specific licensee not authorized in subsections (a)(3)(H)(i) through (iv); however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

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

ii) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by subsection (a)(3)(A)) so that the device is labeled in compliance with 32 Ill. Adm. Code 340.940; however the manufacturer, model number, and serial number must 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 transfer under subsection (a)(3)(I).

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

i) The device remains in use at a particular location. In such case the transferor shall give the transferee a copy of subsection (a), a copy of 32 Ill. Adm. Code 310.40, 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 by a general licensee;

M) Shall furnish a report to the Agency within 30 days after transferring a device containing radioactive material as provided by subsection (a)(3)(L)(i). The 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 (a)(3)(N) 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.

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

A) A person shall register devices (i.e., an electron capture detector, gauge, x-ray fluorescence analyzer, or other measuring, gauging or controlling device) containing at least 370 MBq (10 mCi) of cesium-137, 3.7MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241, or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label;

B) A person shall register with the Agency no later than 30 days after receiving a device identified in subsection (a)(4)(A). Registration information shall be in a format prescribed by the Agency and furnished in accordance with subsection (a)(4)(C);

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 general licensee;

ii) The name, title and phone number of the responsible individual designated as a representative of the general licensee in accordance with subsection (a)(3)(N);

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

iv) The address or locations at which the devices are used or stored;

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;

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

D) Any person who is required by subsection (a)(4) 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 NRC or an Agreement State with respect to a device identified in subsection (a)(4)(A) is exempt from the registration requirement in subsection (a)(4) 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 (a)(1) 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 leakage of, or contamination by, radioactive material and for proper operation of the on-off mechanism and indicator is not required during the storage period. However, the testing required in subsection (a)(3)(B)shall be conducted before the device is returned to service if the device has not been tested within the required test interval.

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 (a)(6)(A) shall apply.

AGENCY NOTE: Record keeping requirements are contained in subsection (a)(3)(D).

7) Failure of any person to comply with the requirements of this subsection (a) 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 (a)(1) does not authorize the manufacture or import of devices containing radioactive material.

9) The general license described in subsection (a)(1) is subject to the provisions of 32 Ill. Adm. Code 310, 326, 331, 340.1210, 340.1220, 340.1260, and 341 and Sections 330.310 and 330.500. Any person who receives, acquires, possesses, uses or transfers radioactive material in a

device pursuant to the general license described in subsection (a)(1) 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 (a)(3)(E) and (a)(9).

b) 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 initially transferred in accordance with a specific license issued under the provisions of Section 330.280(e) or manufactured or assembled in accordance with a specific license issued by NRC or an Agreement State which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the Agency.

2) Persons who receive, acquire, possess or use luminous safety devices pursuant to the general license in subsection (b)(1) 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, repair, or import 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 and 341 and Sections 330.310, 330.400 and 330.500.

c) 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, use, import, or export of byproduct material.

d) 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 (d)(4) and (5), 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 NRC 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 (d)(4) and (5) 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 (d)(4) and (5) 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 (d)(1) through (3) apply only to calibration or reference sources that have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by NRC pursuant to 10 CFR 32.57 or 70.39, or that have been manufactured in accordance with the specifications contained in a specific license issued by the Agency, or an Agreement State pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 70.39.

5) The general licenses provided in subsections (d)(1) through (3) are subject to the provisions of 32 Ill. Adm. Code 310, 340, 341 and 400 and Sections 330.310, 330.400 and 330.500. 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 the following statement or a statement that contains the information called for in this statement:

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission 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.

_____

C) Shall not transfer, abandon or dispose of the source except by transfer to a person authorized by a license from the Agency, NRC or an Agreement 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, import, or export of calibration or reference sources containing americium-241, plutonium or radium-226.

e) 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 (e)(2) through (6), 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 (e)(1) 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 (e)(1) and that the 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 (e)(1) shall comply with the following:

A) The general licensee shall not possess at any one time, pursuant to the general license in subsection (e)(1), 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 (e)(1).

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, NRC or an Agreement 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 (e)(1)(E) 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 (e)(1):

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) or in accordance with the provisions of a specific license issued by NRC or an Agreement 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 this subsection (e) 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:

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

_____

5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of subsection (e)(1) 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) Any person using radioactive material pursuant to the general license of subsection (e)(1) is exempt from the requirements of 32 Ill. Adm. Code 400 and 340, with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in subsection (e)(1)(E) shall comply with the provisions of Sections 340.1010, 340.1210, and 340.1220.

f) 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 NRC 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 (f)(1):

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 NRC 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, repair, or import of strontium-90 in ice detection devices.

4) This general license is subject to the provisions of 32 Ill. Adm. Code 310 and 341 and Sections 330.310, 330.400 and 330.500.

g) 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 (g), 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 (g)(1)(A), antiquities means products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts and healing pads;

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 (1 μCi) of radium-226. For the purposes of this subsection (g)(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 (g)(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 (g)(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 (g)(3)(D);

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 (g)(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.

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

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 submitted 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.

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 the 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:

A) Shall 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; or

B) Shall contain the information identified in Section 330.280(m); or

C) Shall describe, for a sealed source or device containing radioactive material manufactured prior to October 23, 2015, that is not registered with NRC in accordance with 10 CFR 32.210 or with an Agreement State and for which the applicant is unable to provide the information described in Section 330.280(m)(3):

i) The information required by Section 330.280(m)(3) 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; or

D) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with Section 330.280(m)(7), may describe only the manufacturer, model number, radionuclide and quantity; or

E) If it is not feasible to identify each sealed source and device individually, may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

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 signed acknowledgement from the facility owner or authorized representative of the owner that the owner is aware 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: Subsection 10(11) of the Radiation Protection Act of 1990, 420 ILCS 40, requires the Agency to provide written notice of an application for a new license for a fixed location facility or a license amendment for a new location for a facility to the municipality, or county where appropriate, where the facility is located.

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), when applicable.

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

1) The completeness of the application or amendment request;

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.

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 1800 and the requirements of the Freedom of Information Act [5 ILCS 140].

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

EFFECTIVE DATE
DEC 21 2021
SOS-CODE DIV.

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;

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

A) Compliant with the U.S. Food and Drug Administration (FDA) registration requirements 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 Part 207;

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

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

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 commits to 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 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 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):

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), or an individual under the supervision of an authorized nuclear pharmacist as specified in subsection (c)(15).

B) May allow a pharmacist to work as an authorized nuclear pharmacist if the following conditions are met:

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

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

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

C) May designate a pharmacist (as defined in 32 Ill. Adm. Code 310) 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.

D) Shall provide to the Agency, no later than 30 days after the date a licensee allows an individual to work as an authorized nuclear pharmacist under subsections (c)(6)(B)(i) or (iii), a copy of the individual's State of Illinois pharmacist license and:

i) A copy of each individual's certification by a specialty board whose certification process has been recognized by

the U.S. Nuclear Regulatory Commission or an Agreement State as specified in subsection (c)(18)(A); or

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

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

iv) A permit issued by a licensee or U.S. Nuclear Regulatory Commission master material permittee of broad scope or 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;

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 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) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 32 Ill. Adm. Code 335.4020. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in Section 335.4020(a) at the time of generator elution, in accordance with Section 335.4020(d);

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 authorized to distribute radiopharmaceuticals shall ensure that radiopharmaceuticals are dispensed only under the prescription of a physician who is authorized by 32 Ill. Adm. Code 335 to use the radiopharmaceuticals. The licensee shall verify that the physician is authorized to receive the prescribed radiopharmaceutical prior to transfer;
AGENCY NOTE: In accordance with 32 Ill. Adm. Code 335.40(b), licensees authorized for medical use of radiopharmaceuticals may permit work as an authorized user in limited circumstances without first obtaining an amendment. Therefore, possession of the recipient's latest radioactive material license may not list all authorized users.

14) A licensee shall apply for and shall 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 as allowed by 32 Ill. Adm. Code 335.30(b)(2) 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 user or 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 this subsection (c)(15) is responsible for the acts and omissions of the supervised individual;

16) Authority and responsibilities for the radiation protection program.

A) In addition to the radiation protection program requirements in 32 Ill. Adm. Code 340.110, a licensee's management shall approve in writing:

i) Requests for a license application, renewal, or amendment before submittal to the Agency;

ii) Any individual before allowing that individual to work as an authorized nuclear pharmacist; and

iii) Radiation protection program changes that do not require a license amendment.

B) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

C) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under subsections (c)(17) and (c)(21), to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in subsection (G), if the licensee takes the actions required in subsections (B), (D), (E), and (F) and notifies the Agency no later than 30 days after allowing the individual to function as a temporary Radiation Safety Officer.

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

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

i) Identify radiation safety problems;

ii) Initiate, recommend or provide corrective actions;

iii) Stop unsafe operations; and

iv) Verify implementation of corrective actions.

F) A licensee shall retain a record of actions taken under subsections (A), (B), and (D) as follows:

i) A licensee shall retain a record of actions taken by the licensee's management in accordance with subsection (c)(16)(A) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

ii) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by subsection (c)(16)(E), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by subsection (c)(16)(B), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

iii) For each Associate Radiation Safety Officer appointed under subsection (c)(16)(B), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

17) Training for Radiation Safety Officer and Associate Radiation Safety Officer. Except as provided in subsection (c)(20), the licensee shall require an individual fulfilling the responsibilities of Radiation Safety Officer, or an individual assigned duties and tasks as an Associate Radiation Safety Officer provided in subsection (c)(16), at a nuclear pharmacy to be an individual who:

A) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in subsection (c)(17)(D). To have its certification process recognized, a specialty board shall require all candidates for certification to :

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

- 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

- Pass an examination administered by diplomates of the specialty board that 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

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

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

- Have 2 years of full-time practical training or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State or in clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in Section 335.9160, 335.9040, or 335.9050; and

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

B) Has completed a structured educational program consisting of

i) 200 hours of classroom and laboratory 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, or Agreement State license or a permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar types and uses of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a U.S. Nuclear Regulatory Commission or an Agreement State license or permit issued by a U.S. Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience shall involve the following:

- 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 instruments used to measure radionuclides;
- Securing and controlling radioactive material;
- Using administrative controls to avoid mistakes in the administration of radioactive material;
- Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- Using emergency procedures to control radioactive material; and
- Disposing of radioactive material; and

iii) Written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in subsections (B)(i), (B)(ii) and (D), and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or Associate Radiation Safety Officer for a nuclear pharmacy license; or

C) Meets the training requirements in subsection (D); and

i) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State under 32 Ill. Adm. Code 335.9150(a), has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer; or

ii) Is an authorized nuclear pharmacist identified on a specific nuclear pharmacy license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; a nuclear pharmacy use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee; and has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer; or

iii) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new nuclear pharmacy license.

D) 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, Associate Radiation Safety Officer, or authorized nuclear pharmacist, as appropriate, who is authorized for the types of use for which the licensee is seeking approval.

18) Training for an authorized nuclear pharmacist. Except as provided in subsection (c)(19), the licensee shall require the 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. To be recognized, a specialty board shall require a candidate for certification to:

i) Graduate from a pharmacy program accredited by the American Council of Pharmaceutical Education (ACPE) or pass 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 of the specialty board, that evaluates knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research, and development; or

B) Has completed 700 hours in a structured educational program consisting of:

i) 200 hours of classroom and laboratory 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 material; use of procedures to prevent or minimize radioactive contamination and use of proper decontamination procedures; and

iii) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (c)(18)(B)(i) and (ii) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist;

19) An individual identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, or Agreement 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 on or before January 14, 2022 need not comply with the training requirements in subsection (c)(18);

20) Training for Experienced Radiation Safety Officer, nuclear pharmacist, or authorized nuclear pharmacist.

A) An individual identified on an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2022, need not comply with the training requirements of 32 Ill. Adm. Code 335.9010,

335.9150, or subsection (c)(18), respectively, except the Radiation Safety Officers identified in this subsection shall meet the training requirements in 32 Ill. Adm. Code 335.9010(e) or 335.9150(d) for any material or uses for which they were not authorized prior to this date.

B) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics, American Board of Radiology, American Board of Nuclear Medicine, American Board of Science in Nuclear Medicine, Board of Pharmaceutical Specialties in Nuclear Pharmacy, American Board of Medical Physics in radiation oncology physics, Royal College of Physicians and Surgeons of Canada in nuclear medicine, American Osteopathic Board of Radiology, or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of subsection (c)(17) to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an Agency license for those materials and uses that these individuals performed on or before October 24, 2005.

C) A Radiation Safety Officer or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as recognized by NRC, need not comply with the training requirements of subsection (c)(17) or (c)(18), respectively, when performing the same uses. A nuclear pharmacist, who only prepared radioactive drugs containing accelerator-produced radioactive material at the locations and during the time period identified in this subsection, qualifies as an authorized nuclear pharmacist for those materials and uses performed before these dates, for the purposes of this Section.

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

21) Recentness of Training. The training and experience specified in subsections (c)(17) and (c)(18) shall have been obtained within the 7 years preceding the date of application or the individual shall 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:

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

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)(4) 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.

24) A licensee shall satisfy the labeling requirements in subsection (c)(5).

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 whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on NRC's website.

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

EFFECTIVE DATE
DEC 21 2021
SOS-CODE DIV.

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).

f) A licensee possessing a Type A specific license of broad scope for medical use, issued under this Part, is exempt from:

1) The provisions of 32 Ill. Adm. Code 335.40(b);

2) The provisions of 32 Ill. Adm. Code 335.40(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

3) The provisions of 32 Ill. Adm. Code 335.45(a);

4) The provisions of 32 Ill. Adm. Code 335.45(b)(1) for an authorized user, an authorized medical physicist, or an ophthalmic physicist; and

5) The provisions of 32 Ill. Adm. Code 335.45(b)(5).

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

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:

i) a description of the product or material into which the radioactive material will be introduced;

ii) intended use of the radioactive material and the product or material into which it is introduced;

iii) method of introduction;

iv) initial concentration of the radioactive material in the product or material;

v) control methods to assure that no more than the specified concentration is introduced into the product or material;

vi) estimated time interval between introduction and transfer of the product or material; and

vii) 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 the preceding report was filed; or

B) The licensee has:

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).

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 one 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 NRC (10 CFR 30.14) or of an Agreement State, except in accordance with a specific license issued under 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 DC 20555.

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

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 DC 20555.

d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under Section 330.220(a).

AGENCY NOTE: Subsection (p) describes 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(a) or equivalent regulations of NRC or an Agreement State will be approved if:

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

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 one 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 one 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 contains 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 on 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 the 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:

The receipt, possession, use and transfer of this device, Model___, Serial No.____, 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.

OR

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.

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)(73 Fed.Reg. 42673, July 23, 2008) 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.

F) The device has been registered in the Sealed Source and Device Registry in accordance with subsection (m)(2).

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 six 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 three months for devices containing sources designed to emit alpha particles and six months for all other devices. In the event the applicant desires that the device be required to be tested at longer intervals, the applicant shall include in the application sufficient information to demonstrate that those 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 Section 330.220(a), or under equivalent regulations of NRC or an Agreement 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 the activity or activities and bases for the estimates. The submitted information shall demonstrate that performance of the 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) to distribute devices to generally licensed persons shall provide the information in this subsection (d)(4) to each person to whom a device is to be transferred for possession and use under the general license in Section 330.220(a). 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(a);

AGENCY NOTE: If certain provisions of Section 330.220(a) 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, 340.1220 and 340.1260;

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(a) in the regulations of NRC or an Agreement 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 NRC or the equivalent regulations of an Agreement State. NRC regulations are 10 CFR 31.5(73 Fed. Reg. 42673, July 23, 2008), 10 CFR 31.2(65 Fed. Reg. 79187, December 18, 2000), 10 CFR 30.51(61 Fed. Reg. 24673, May 16, 1996), 10 CFR 20.2201(67 Fed. Reg. 3585, January 25, 2002) and 10 CFR 20.2202(63 Fed. Reg. 39483, July 23, 1998). If NRC regulations are provided to a prospective general licensee in lieu of applicable Agreement State regulations, they shall be accompanied by a note explaining that use of the device is regulated by the Agreement 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 NRC and most Agreement States to take escalated enforcement action for improper disposal; and

E) The name or title, address and phone number of the contact at NRC or Agreement 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 transferred device shall meet the labeling requirements of subsections (d)(1)(C), (D) and (E).

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

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(b) will be approved if:

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

B) The applicant satisfies the requirements of the following regulations of NRC or their equivalent. The regulations are 10 CFR 32.53 (77 Fed. Reg. 43693, July 25, 2012), 10 CFR 32.54 (63 Fed. Reg. 39483, July 23, 1998) and 10 CFR 32.55 (77 Fed. Reg. 43693, July 25, 2012).

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(b) or equivalent regulations of NRC 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. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the Agency.

3) Each person licensed under this subsection (e) shall also file an annual report with the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, U.S. Nuclear Regulatory Commission, Washington DC 20555 by the appropriate method listed in 10 CFR 30.6, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under Section 330.220(b). The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed by July 30. If no transfers have been made to persons generally licensed under Section 330.220(b) during the reporting period, the report shall so indicate.

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(d). 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(d) will be approved if:

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

2) The applicant satisfies the requirements of 10 CFR 32.57 (77 Fed. Reg. 43693, July 25, 2012) and 10 CFR 70.39 (43 Fed. Reg. 6925, February 17, 1978). The applicant shall also certify that it will satisfy, and subsequently satisfies, the requirements of 10 CFR 32.58 and 32.59 (77 Fed. Reg. 43694, July 25, 2012).

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(e), or equivalent regulations of NRC or an Agreement State, will be approved if:

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

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 following statement, or a statement that contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

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 NRC or of a state with which NRC has entered into an agreement for the exercise of regulatory authority.

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 that 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 NRC 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(f) will be approved if:

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

2) The criteria of 10 CFR 32.61 and 32.62(77 Fed. Reg. 43694, July 25, 2012) 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 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;

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; maximum activity per vial, syringe, generator or other container of the radioactive drug; and the shielding provided by the packaging to show the packaging is appropriate for safe handling and storage of radiopharmaceuticals by medical use 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 that 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 NRC or an Agreement 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 those 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 those reagent kits approved by the Agency for use by persons licensed pursuant to Section 330.260(a), (b) or (c) 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) 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;

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) and 32 Ill. Adm. Code 335.4010 or under equivalent licenses of NRC or an Agreement 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) 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;

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 and 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 that are too lengthy for the 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), (b) or (c) and 32 Ill. Adm. Code 335.2040, 335.2140, 335.6010, 335.7010 and 335.8010 or under equivalent licenses of NRC or an Agreement 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;

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; and

6) The source or device has been registered in the Sealed Source and Device Registry in accordance with subsection (m)(2).

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(g) or equivalent regulations of NRC or an Agreement State will be approved if:

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

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 one 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 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 NRC 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(g) 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(g); or

ii) A copy of the general license contained in NRC's or Agreement State's regulation equivalent to Section 330.210(g) and a copy of NRC's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Section 330.210(g) and a copy of the form "Registration Certificate – Use of Depleted Uranium Under General License", to each person to whom he or she transfers depleted uranium in a product or device for use pursuant to the general license of NRC or an Agreement State, with a note explaining that use of the product or device is regulated by NRC or an Agreement State under requirements substantially the same as those in Section 330.210(g);

E) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in Section 330.210(g). The 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 product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Section 330.210(g) 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 the product or device is transferred to the generally licensed person. The licensee shall report:

i) To NRC, all transfers of industrial products or devices to persons for use under NRC 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(g);

iii) To NRC, 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 the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Section 330.210(g) or equivalent regulations of NRC 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).

m) Special Requirements for License to Manufacture or Initially Distribute Sealed Sources or Devices Containing Sealed Sources

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

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

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.

2) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in the NRC "Registry of Radioactive Sealed Sources and Devices".

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

4) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Other subsections of this Section have specific criteria that apply to certain products.

5) After completion of the evaluation, the Agency issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license, as applicable, for the category of certificate.

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

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

   B) The provisions of the registration certificate.

7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

   A) Calibration and reference sources containing no more than:

i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

ii) 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

B) The intended recipients are qualified by training and experience, and have sufficient facilities and equipment, to safely use and handle the requested quantity of radioactive material in any form, in the case of unregistered sources, or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment, to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

i) The intended recipients are licensed under Section 330.270 or comparable provisions of NRC or an Agreement State; or

ii) The recipients are authorized for research and development; or

iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

8) After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in this Section. The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information requested.

9) A certificate holder who no longer manufactures or initially transfers any of the sealed sources or devices covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. The request must be made to the Agency by an appropriate method listed in 32 Ill. Adm. Code 310.110 and must normally be made no later than two years after initial distribution of all the sources or devices covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than 2 years after that transfer, the certificate holder shall request inactivation of the

certificate within 90 days after this determination and briefly describe the circumstances of the delay.

10) If a distribution license is to be terminated in accordance with Section 330.325, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. A request for inactivation of certificates must indicate that the license is being terminated and include the associated specific license number.

11) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer the sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

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 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 following statement, or a statement that contains the information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure that accompanies the package:

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 NRC or of a state with which NRC has entered into an agreement for the exercise of regulatory authority.

o) Requirements for License to Initially Transfer Source Material for Use Under the "Small Quantities of Source Material" General License

1) An application for a specific license to initially transfer source material for use under Section 330.210 will be approved if:

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

   B) The applicant submits adequate information on the methods to be used for quality control, labeling and providing safety instructions to recipients.

2) Each person licensed under this subsection (o) shall label the immediate container of each quantity of source material with the type and quantity of source material and the words "radioactive material".

3) Each person licensed under this subsection (o) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

4) Each person licensed under this subsection (o) shall provide the information specified in this subsection (o)(4) to each person to whom source material is transferred for use under Section 330.210. This information shall be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

   A) A copy of Sections 330.210 and 330.400; and

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

5) Each person licensed under this subsection (o) shall report transfers as follows:

   A) File a report with the Agency that includes the following information:

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

      ii) For each general licensee under Section 330.210 to whom greater than 50 grams (0.11 pounds) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is

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

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

B) File a report with each responsible Agreement State or NRC, as appropriate, that identifies all persons, operating under provisions equivalent to Section 330.210, to whom greater than 50 grams (0.11 pounds) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State or NRC licensees:

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

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

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

C) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under Section 330.210, or equivalent Agreement State or NRC provisions, during the current period, a report shall be submitted to the Agency indicating so. If no transfers have been made to general licensees in a particular Agreement State during the reporting period, this information shall be reported to each responsible Agreement State agency or NRC upon request.

6) Each person licensed under this subsection (o) shall maintain all information that supports the reports required by subsection (o)(5) concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Agreement State agency or NRC.

p) Material Transfer Reports and Records

Each person licensed under subsection (d) to distribute devices to generally licensed persons shall comply with the requirements of this subsection (p).

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(a) or the equivalent regulations of NRC or an Agreement State;

B) To the Agency and to the responsible regulatory agency all receipts of devices from persons generally licensed under Section 330.220(a) or the equivalent regulations of NRC or an Agreement 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) 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 (p). These records shall be maintained for 5 years following the recorded event.

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

EFFECTIVE DATE
DEC 21 2021
SOS-CODE DIV.

Section 330.310 Terms and Conditions of Specific and General Licenses

a) Each specific or general license issued pursuant to this Part shall be subject to all applicable license conditions, provisions of the Act, and all applicable rules, regulations and orders of the Agency.

b) Each person granted a general license by this Part shall provide information required by the Agency to track the location and use of generally-licensed radioactive material. The information shall be in the format prescribed by the Agency, shall be complete and accurate, and shall be due within the time frame indicated on the notification. In accordance with 32 Ill. Adm. Code 310.50, the Agency may inspect and investigate premises, operations or personnel and have access to or copy records:

1) Of a person who fails to provide information as required by this subsection (b); or

2) For the purpose of evaluating past, current or potential hazards to the public health, workers or the environment resulting from radiation.

c) No specific license issued or granted to any person pursuant to this Part and no right to possess or use radioactive material granted to any person by any specific license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the specific license to any other person unless the Agency:

1) Is provided notification, including the identity and technical qualifications of the proposed transferee, not later than 90 days prior to the transfer;

2) Finds that the proposed transfer, assignment or disposal is in accordance with the provisions of the Act;

3) Consents in writing to the proposed transfer, assignment or disposal; and

4) Finds the transferee, when applicable, to be compliant with the requirements of 32 Ill. Adm. Code 326.

AGENCY NOTE: Agency consent is required prior to any transfer or assignment of a specific license. A purported transfer or assignment without prior written consent may subject the purported transferor or assignor to penalties for violating this Section. Likewise, a purported transferee or assignee may also be subject to penalties if it does not have a valid specific license and possesses radioactive material or performs activities requiring a valid specific license.

d) Upon approval from the Agency under subsection (c)(2) for transfer, assignment or disposal of a specific license, the transferor shall ensure the following information is provided to the transferee:

1) The radioactive material license and all documents referenced in the license;

2) Records maintained in accordance with 32 Ill. Adm. Code 340, Subpart L, inventory records, and any other records required by subsections (k) and (l); and

3) Any other information required by the Agency pursuant to the approval granted.

e) Each person licensed by the Agency pursuant to this Part shall confine use and possession of the material licensed to the locations and purposes authorized in the license and, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site and/or facility of operation, including the subsurface.

f) Each person issued a specific license pursuant to this Part shall maintain the license in accordance with the requirements of Section 330.320.

g) When temporary jobsites are authorized on a specific license, radioactive material may be used at temporary jobsites, in areas not under exclusive federal jurisdiction, throughout the State of Illinois.

AGENCY NOTE: Authorization for use of byproduct radioactive materials at jobsites under exclusive federal jurisdiction must be obtained from NRC, either by filing an NRC Form-241 in accordance with 10 CFR 150.20(b), "Recognition of Agreement State Licenses", or by applying for a specific license from NRC. Also, specific licenses issued by the Agency do not authorize activities in other states. Before radioactive materials can be used at a temporary jobsite in another state, a license must be obtained from the appropriate state or federal regulatory agency.

h) Each person issued a specific license pursuant to this Part shall apply for an appropriate license amendment not later than 30 days after a Radiation Safety Officer permanently discontinues performance of duties under the license.

i) Notification

1) Each specific licensee shall notify the Agency in writing not later than 60 days after principal activities involving the use of radioactive materials, including sealed sources and devices, at the site or in a separate building or outdoor area have not occurred for a period of 2 years, and the licensee has not decontaminated the site or properly disposed of the sealed sources or devices.

AGENCY NOTE: Principal activities are those originally authorized on the license for that site or location. For example, licensees could not store radioactive material in an otherwise unused building to avoid end-of-use decommissioning, unless storage was a principal activity for that building.

2) This notification shall include a description of the location of the site, building or outdoor area and a plan for reclaiming or decommissioning these facilities (including a proposed schedule) for release in accordance with applicable regulations. The notification shall include an evaluation of any changes, if required, to financial assurance arrangements submitted in accordance with 32 Ill. Adm. Code 326. Upon approval of the plan by the Agency, implementation shall begin within 6 months and be completed within 24 months after approval (unless the Agency approves a different schedule).

AGENCY NOTE: 32 Ill. Adm. Code 340.1310 requires licensees to notify the Agency no less than 30 days before vacating or relinquishing possession or control of premises that may have been contaminated with radioactive material.

3) For a device with a shutter that 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, as applicable to devices in storage, shall be conducted in accordance with 32 Ill. Adm. Code 340.410.

4) 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 of subsection (i)(3) shall apply.

j) Notification of Bankruptcy

1) Each specific or general licensee shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

A) The licensee;

B) An entity (as the term is defined in 11 USC 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

C) An affiliate (as the term is defined in 11 USC 101(2)) of the licensee.

2) This notification shall indicate:

A) The bankruptcy court in which the petition for bankruptcy was filed;

B) The date of the filing of the petition;

C) The chapter under which the bankruptcy petition has been filed;

D) The name, address and phone number of the bankruptcy trustee (if a trustee has been named at the time of the notification);

E) Whether the licensed radiation source remains in the possession and control of the licensee and whether any change in possession or control is expected or contemplated;

F) The name of the person in possession and control of the licensed radiation source if the licensee no longer maintains possession or control; and

G) Whether the Agency has been named in the bankruptcy petition either as a creditor or in some other capacity.

k) Recordkeeping Requirements for Potentially Contaminated Areas. Except for areas containing only sealed sources, provided the sources have not leaked, or no contamination remains after any leakage, and except for areas where only radioactive materials with half-lives less than 90 days were used or stored, each specific licensee shall keep:

1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site, when contamination remains after any cleanup procedures or when there is reasonable likelihood the contaminants may have spread to inaccessible areas (as in the case of possible seepage into porous materials such as concrete). These records must include the location and any known information on identification of involved radionuclides, quantities, chemical and physical forms, and concentrations.

2) Drawings and subsequent modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination, such as buried or enclosed pipes, that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

l) Each licensee shall maintain the following records, if applicable:

1) Records of all areas where low-level radioactive wastes were buried, including areas previously authorized by and documented pursuant to 10 CFR 20.2108.

2) Records of the Agency-approved cost estimate for the amount certified for reclaiming and the associated reclamation plan, for licensees required by 32 Ill. Adm. Code 326 to secure financial assurance arrangements.

3) All records required to be maintained pursuant to 32 Ill. Adm. Code Chapter II, Subchapters b and d.

m) To lawfully obtain termination for a specific license, each licensee shall meet the termination requirements of this Part.

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

EFFECTIVE DATE
DEC 21 2021
SOS-CODE DIV.

Section 330.340 Amendment of Licenses at Request of Licensee

a) Applications for amendment of a license shall be filed in accordance with Section 330.240 and shall specify the purpose for which the licensee desires the license to be amended and the grounds for the amendment.

b) Except as otherwise authorized by the Agency, the licensee shall receive an amendment before the licensee:

1) Receives, uses, or transfers radioactive material for a type of use not authorized on the licensee's current license.

2) Adds or changes the Radiation Safety Officer.

3) Receives radioactive material in excess of the license possession limits or in a form not stated on the current license.

4) Adds to or changes areas of use or storage locations, including change of address.

5) Revises procedures identified in the current license.

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

Section 330.APPENDIX D Limits for Licenses of Broad Scope (Section 330.270)

	Column I		Column II	
Radioactive Material	GBq	Ci	GBq	Ci
Antimony-122	37	1	0.37	0.01
Antimony-124	37	1	0.37	0.01
Antimony-125	37	1	0.37	0.01
Arsenic-73	370	10	3.7	0.1
Arsenic-74	37	1	0.37	0.01
Arsenic-76	37	1	0.37	0.01
Arsenic-77	370	10	3.7	0.1
Barium-131	370	10	3.7	0.1
Barium-140	37	1	0.37	0.01
Beryllium-7	370	10	3.7	0.1
Bismuth-210	3.7	0.1	0.037	0.001
Bromine-82	370	10	3.7	0.1
Cadmium-109	37	1	0.37	0.01
Cadmium-115m	37	1	0.37	0.01
Cadmium-115	370	10	3.7	0.1
Calcium-45	37	1	0.37	0.01
Calcium-47	370	10	3.7	0.1
Carbon-14	3,700	100	37	1.
Cerium-141	370	10	3.7	0.1

Cerium-143	370	10	3.7	0.1
Cerium-144	3.7	0.1	0.037	0.001
Cesium-131	3,700	100	37	1
Cesium-134m	3,700	100	37	1
Cesium-134	3.7	0.1	0.037	0.001
Cesium-135	37	1	0.37	0.01
Cesium-136	370	10	3.7	0.1
Cesium-137	3.7	0.1	0.037	0.001
Chlorine-36	37	1	0.37	0.01
Chlorine-38	3,700	100	37	1.
Chromium-51	3,700	100	37	1.
Cobalt-57	370	10	3.7	0.1
Cobalt-58m	3,700	100	37	1.
Cobalt-58	37	1	0.37	0.01
Cobalt-60	3.7	0.1	0.037	0.001
Copper-64	370	10	3.7	0.1
Dysprosium-165	3,700	100	37	1.
Dysprosium-166	370	10	3.7	0.1
Erbium-169	370	10	3.7	0.1
Erbium-171	370	10	3.7	0.1
Europium-152 (9.2 h)	370	10	3.7	0.1
Europium-152 (13 y)	3.7	0.1	0.037	0.001

	Column I		Column II	
Radioactive Material	GBq	Ci	GBq	Ci
Europium-154	3.7	0.1	0.037	0.001
Europium-155	37	1	0.37	0.01
Fluorine-18	3,700	100	37	1.
Gadolinium-153	37	1	0.37	0.01
Gadolinium-159	370	10	3.7	0.1
Gallium-72	370	10	3.7	0.1
Germanium-71	3,700	100	37	1.
Gold-198	370	10	3.7	0.1
Gold-199	370	10	3.7	0.1
Hafnium-181	37	1	0.37	0.01
Holmium-166	370	10	3.7	0.1
Hydrogen-3	3,700	100	37	1.
Indium-113m	3,700	100	37	1.
Indium-114m	37	1	0.37	0.01
Indium-115m	3,700	100	37	1.
Indium-115	37	1	0.37	0.01
Iodine-125	3.7	0.1	0.037	0.001
Iodine-126	3.7	0.1	0.037	0.001
Iodine-129	3.7	0.1	0.037	0.001
Iodine-131	3.7	0.1	0.037	0.001
Iodine-132	370	10	3.7	0.1

Iodine-133	37	1	0.37	0.01
Iodine-134	370	10	3.7	0.1
Iodine-135	37	1	0.37	0.01
Iridium-192	37	1	0.37	0.01
Iridium-194	370	10	3.7	0.1
Iron-55	370	10	3.7	0.1
Iron-59	37	1	0.37	0.01
Krypton-85	3,700	100	37	1.
Krypton-87	370	10	3.7	0.1
Lanthanum-140	37	1	0.37	0.01
Lutetium-177	370	10	3.7	0.1
Manganese-52	37	1	0.37	0.01
Manganese-54	37	1	0.37	0.01
Manganese-56	370	10	3.7	0.1
Mercury-197m	370	10	3.7	0.1
Mercury-197	370	10	3.7	0.1
Mercury-203	37	1	0.37	0.01
Molybdenum-99	370	10	3.7	0.1
Neodymium-147	370	10	3.7	0.1
Neodymium-149	370	10	3.7	0.1
Nickel-59	370	10	3.7	0.1

Column I Column II

Radioactive Material	GBq	Ci	GBq	Ci
Nickel-63	37	1	0.37	0.01
Nickel-65	370	10	3.7	0.1
Niobium-93m	37	1	0.37	0.01
Niobium-95	37	1	0.37	0.01
Niobium-97	3,700	100	37	1.
Osmium-185	37	1	0.37	0.01
Osmium-191m	3,700	100	37	1.
Osmium-191	370	10	3.7	0.1
Osmium-193	370	10	3.7	0.1
Palladium-103	370	10	3.7	0.1
Palladium-109	370	10	3.7	0.1
Phosphorus-32	37	1	0.37	0.01
Platinum-191	370	10	3.7	0.1
Platinum-193m	3,700	100	37	1.
Platinum-193	370	10	3.7	0.1
Platinum-197m	3,700	100	37	1.
Platinum-197	370	10	3.7	0.1
Polonium-210	0.37	0.01	0.0037	0.0001
Potassium-42	37	1	0.37	0.01
Praseodymium-142	370	10	3.7	0.1
Praseodymium-143	370	10	3.7	0.1
Promethium-147	37	1	0.37	0.01

Promethium-149	370	10	3.7	0.1
Radium-226	0.37	0.01	0.0037	0.0001
Rhenium-186	370	10	3.7	0.1
Rhenium-188	370	10	3.7	0.1
Rhodium-103m	37,000	1,000	370	10.
Rhodium-105	370	10	3.7	0.1
Rubidium-86	37	1	0.37	0.01
Rubidium-87	37	1	0.37	0.01
Ruthenium-97	3,700	100	37	1.
Ruthenium-103	37	1	0.37	0.01
Ruthenium-105	370	10	3.7	0.1
Ruthenium-106	3.7	0.1	0.037	0.001
Samarium-151	37	1	0.37	0.01
Samarium-153	370	10	3.7	0.1
Scandium-46	37	1	0.37	0.01
Scandium-47	370	10	3.7	0.1
Scandium-48	37	1	0.37	0.01
Selenium-75	37	1	0.37	0.01
Silicon-31	370	10	3.7	0.1
Silver-105	37	1	0.37	0.01
	Column I		Column II	
Radioactive Material	GBq	Ci	GBq	Ci
Silver-110m	3.7	0.1	0.037	0.001

Silver-111	370	10	3.7	0.1
Sodium-22	3.7	0.1	0.037	0.001
Sodium-24	37	1	0.37	0.01
Strontium-85m	37,000	1,000	370	10
Strontium-85	37	1	0.37	0.01
Strontium-89	37	1	0.37	0.01
Strontium-90	0.37	0.01	0.0037	0.0001
Strontium-91	370	10	3.7	0.1
Strontium-92	370	10	3.7	0.1
Sulfur-35	370	10	3.7	0.1
Tantalum-182	37	1	0.37	0.01
Technetium-96	370	10	3.7	0.1
Technetium-97m	370	10	3.7	0.1
Technetium-97	370	10	3.7	0.1
Technetium-99m	3,700	100	37	1.
Technetium-99	37	1	0.37	0.01
Tellurium-125m	37	1	0.37	0.01
Tellurium-127m	37	1	0.37	0.01
Tellurium-127	370	10	3.7	0.1
Tellurium-129m	37	1	0.37	0.01
Tellurium-129	3,700	100	37	1.
Tellurium-131m	370	10	3.7	0.1
Tellurium-132	37	1	0.37	0.01

Terbium-160	37	1	0.37	0.01
Thallium-200	370	10	3.7	0.1
Thallium-201	370	10	3.7	0.1
Thallium-202	370	10	3.7	0.1
Thallium-204	37	1	0.37	0.01
Thulium-170	37	1	0.37	0.01
Thulium-171	37	1	0.37	0.01
Tin-113	37	1	0.37	0.01
Tin-125	37	1	0.37	0.01
Tungsten-181	37	1	0.37	0.01
Tungsten-185	37	1	0.37	0.01
Tungsten-187	370	10	3.7	0.1
Vanadium-48	37	1	0.37	0.01
Xenon-131m	37,000	1,000	370	10.
Xenon-133	3,700	100	37	1.
Xenon-135	3,700	100	37	1.
Ytterbium-175	370	10	3.7	0.1
Yttrium-90	37	1	0.37	0.01

	Column I		Column II	
Radioactive Material	GBq	Ci	GBq	Ci
Yttrium-91	37	1	0.37	0.01
Yttrium-92	370	10	3.7	0.1

Yttrium-93	37	1	0.37	0.01
Zinc-65	37	1	0.37	0.01
Zinc-69m	370	10	3.7	0.1
Zinc-69	3,700	100	37	1.
Zirconium-93	37	1	0.37	0.01
Zirconium-95	37	1	0.37	0.01
Zirconium-97	37	1	0.37	0.01

Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.

3.7 0.1 0.037 0.001

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

EFFECTIVE DATE
DEC 21 2021
SOS-CODE DIV.

Section 330.900 Reciprocal Recognition of Licenses

a) Subject to this Part, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State is hereby granted a general license to conduct the activities authorized in such licensing document within this State, in areas not under exclusive federal jurisdiction, for a period not in excess of 180 days in any 12-month period, provided that:

1) A current copy of the licensing document is on file with the Agency and activities authorized by the document are not limited to specified installations or locations.

2) The out-of-state licensee notifies the Agency by telephone, facsimile, or as otherwise provided in 32 Ill. Adm. Code 310.110 prior to engaging in such activities. Notification shall indicate the following:

A) Contact person

B) Phone number of contact

C) Company name and address

D) Company contact person on-site

E) License number of applicant or registrant

F) Licensing authority

G) Expiration date of applicant's or registrant's license

H) Dates of work at temporary job site

I) Client or facility name and address

K) Client or facility contact person and phone number

L) Proposed use and names of authorized users, their unique identification that can be independently verified (e.g., driver's license number, employee ID, work permit number, etc.), or if no other identification is available, the social security number of the individual; and

M) Device manufacturer, model, radionuclide, source model, and activity.

3) If initial notification was by telephone, the out-of-state licensee shall submit to the Agency, within 10 days following notification, a letter containing the information as specified in subsection (a)(2). Upon receipt from the out-of-state licensee of a written request containing a schedule of activities to be conducted within Illinois, the Agency shall waive the requirement for additional notifications of activities on that schedule during the 12-month period following the receipt of the initial notification from a person engaging in activities under the general license provided in this Section.

4) The out-of-state licensee complies with 32 Ill. Adm. Code: Chapter II and with all the terms and conditions of the licensing document, except any terms and conditions that may be inconsistent with 32 Ill. Adm. Code: Chapter II.

5) The out-of-state licensee supplies other information as the Agency may request to show compliance with 32 Ill. Adm. Code: Chapter II.

6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this Section, except by transfer to a person:

A) Specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission or another state to receive such material; or

B) Exempt from the requirements for a license for such material under Section 330.40(a).

b) In addition to the provisions of subsection (a), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install or service a device described in Section 330.220(a) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service the device in this State, provided that:

1) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or another state;

2) The person shall assure that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bear a statement that "Removal of this label is prohibited".

c) The Agency may withdraw, limit or qualify its acceptance of any specific license issued by the U.S. Nuclear Regulatory Commission or another state, or any product distributed pursuant to the license, if the Agency determines that had the person been licensed in Illinois by the Agency, the license would have been subject to action under Section 330.500.

(Source: Amended at 46 Ill. Reg. 866, effective DEC 21 2021)

EFFECTIVE DATE
DEC 21 2021
SOS-CODE DIV.