IEMA
Illinois Emergency Management Agency

James K. Joseph, Director

Ms. Vicki Thomas
Executive Director
Joint Committee on Administrative Rules
700 Stratton Office Building
Springfield, Illinois 62706

Re: 32 Ill. Adm. Code 330

Dear Ms. Thomas:

This SECOND NOTICE is for the Illinois Emergency Management Agency's Proposed Amendments pertaining to Licensing of Radioactive Material.

In accordance with Sections 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Illinois Emergency Management Agency states as follows:

1) The name of the agency is the Illinois Emergency Management Agency.

2) The title and citation of the proposed amendments are Licensing of Radioactive Material, 32 Ill. Adm. Code 330.

3) The First Notice was published on May 15, 2015, in Vol. 39, Issue 20 of the Illinois Register, beginning at p. 6748.

4) The Agency has accepted all changes made by JCAR and they are included in the text.

5) The Agency received notification from the Office of the Secretary of State, Administrative Code Division that the Division had reviewed the Proposed Rules and found that the rules comply with codification requirements. (See Attachment A: Memorandum dated May 8, 2015)

6) The Proposed Amendment does not contain incorporations by reference pursuant to Section 100/5-75 of the Illinois Administrative Procedure Act.

7) The Agency received no comments regarding this rulemaking from businesses identifying themselves as small businesses pursuant to Section 100/5-40(c) of the IAPA. Therefore, a Final Regulatory Flexibility Analysis was not prepared.

8) In order to comply with the requirements of Section 100/5-30 of the Administrative Procedure Act and 1 Ill. Adm. Code 220.285, the Agency emailed a copy of the proposed Amendments to the members of the affected community.

9) The Agency did not receive any comments regarding this rulemaking during the First Notice Period.

10) This Amendment will: adds new categories of exempt devices; clarifies restrictions on sale or distribution of exempt items; adds language confirming practices for manufacturing, evaluation, quality assurance and registration of new products; and clarifies reporting requirements for manufacturers of tritium and promethium devices.

These rules are required for compatibility with the U. S. Nuclear Regulatory Commission (NRC) pursuant to RATS ID 2012-3 and 2012-4 (77 FR 39899 published 7/6/2012 and 77 FR 43666 published 7/25/2012). The proposed amendments have been reviewed and approved by the NRC.

11) Joint Committee questions may be directed to Louise Conway, Staff Attorney at 785-9876 or Traci Burton, Paralegal Assistant at 785-9860, telefax number 524-3698.

12) The Joint Committee on Administrative Rules did not request the Agency to complete a State Mandates Act Questionnaire.

Sincerely,

Traci Burton
Rules Coordinator

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

PART 330
LICENSING OF RADIOACTIVE MATERIAL

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330.360 Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of This Part (Repealed)
330.370 Persons Possessing Accelerator-Produced or Naturally-Occurring Radioactive Material on Effective Date of This Part (Repealed)
330.400 Transfer of Material
330.500 Modification and Revocation of Licenses
330.900 Reciprocal Recognition of Licenses
330.950 Nationally Tracked Sources

SUBPART D: TRANSPORTATION

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330.1000 Transportation of Radioactive Materials (Repealed)

330.APPENDIX A Exempt Concentrations
330.APPENDIX B Exempt Quantities
330.APPENDIX C Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release
330.TABLE A Group I (Repealed)
330.TABLE B Group II (Repealed)
330.TABLE C Group III (Repealed)
330.TABLE D Group IV (Repealed)
330.TABLE E Group V (Repealed)
330.TABLE F Group VI (Repealed)
330.APPENDIX D Limits for Broad Licenses (Section 330.270)
330.APPENDIX E List of Specialty Board Certifications Recognized by the Agency Until October 24, 2007 (Repealed)
330.APPENDIX F Nationally Tracked Source Thresholds
330.APPENDIX G Financial Surety Arrangements (Section 330.250(c)(1)(D)) (Repealed)
330.APPENDIX H Wording of Financial Surety Arrangements (Section 330.250(c)(1)(E)) Repealed (Repealed)

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. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 330.40 License Exemption-Radioactive Materials Other Than Source Material

a) Exempt Concentrations

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

2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection (a)(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission (NRC) (10 CFR 30.14) or an Agreement State, except in accordance with a specific license issued pursuant to Section 330.280(a).

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

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b) Exempt Quantities

1) Except as restricted by subsections (b)(2) through (4), any person is exempt from this Part to the extent that person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B. Furthermore, any person is exempt from this Part to the extent that person possesses, uses, transfers or owns radioactive material that was received or acquired before September 25, 1971 under the general license then provided by the regulations of the U.S. Atomic Energy Commission (10 CFR 31.4) or the equivalent regulations of an Agreement State.

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

2) This subsection (b) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

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

4) No person shall, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by the exemption in subsection (b)(1) so that the aggregate quantity exceeds the limits set forth

in Appendix B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by this Part. 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~~D.C.~~ 20555.

c) Exempt Items

1) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products or persons who initially transfer for sale or distribution the following products, any person is exempt from this Part to the extent that he or she receives, possesses, uses, transfers, owns or acquires the following products:

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

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

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

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

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

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

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

vi) 2.22 MBq (60 microCi) of promethium-147 per watch dial or 4.44 MBq (120 microCi) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ii) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's sources may contain one or more radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B, provided that the sum of the fractions shall not exceed unity.

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

F) Ionization chamber smoke detectors containing not more than 37 kBq (1 microCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

G) Static elimination devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material

consisting of a total of not more than 18.5 MBq (500microCi) of polonium-210 per device.

H) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50mCi) of hydrogen-3 (tritium) per device.

I) Devices described in subsections (c)(1)(G) and (H) authorized before October 23, 2015 for use under the general license then provided in Section 330.220(a) and manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Agency or the equivalent regulations of NRC or of an Agreement State.

2) Self-Luminous Products Containing Radioactive Material

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

B) Any person who desires to manufacture, process, produce or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85 or promethium-147 for use under subsection (c)(2)(A) should apply for a license under 10 CFR 32.22 and for a certificate of registration pursuant to 10 CFR 32.210 with NRC.

C~~B~~) Radium-226. Any person is exempt from this Part to the extent that person receives, possesses, uses, transfers or owns articles containing less than 3.7 kBq (100 nCi) of radium-226 that were acquired prior to May 1, 1974.

3) Gas and Aerosol Detectors Containing Radioactive Material

A) Except for persons who manufacture, process, produce or initially transfer for sale and distribution gas and aerosol detectors containing radioactive material, any person is exempt from 32 Ill. Adm. Code: Chapter II, Subchapters b and d to the extent that person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards. The detectors shall be ~~have been~~ manufactured, processed, produced ~~imported~~ or initially transferred in accordance with a specific license issued by NRC~~the U.S. Nuclear Regulatory Commission~~ pursuant to 10 CFR 32.26 that authorizes transfer of the detectors to persons who are exempt from regulatory requirements and who have been issued a certificate of registration in accordance with 10 CFR 32.210 from NRC.

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

B) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State or a former Licensing State shall be considered exempt under subsection (c)(3)(A), provided that the device is labeled in accordance with the specific license and provided further that it meets the requirements of 10 CFR 32.26 in effect at the time of distribution. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by an Agreement State under comparable provisions to NRC's 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

4) Certain Industrial Devices

A) Except for persons who manufacture, process, produce or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from 32 Ill. Adm. Code: Chapter II, Subchapters b and d to the extent that person receives, possesses, uses, transfers, owns or acquires byproduct material, in these certain detecting, measuring, gauging or controlling devise and certain devices for producing an ionized atmosphere, and manufactured, processed, produced or initially transferred in accordance with a specific license issued under NRC's 10 CFR 32.30, which license authorized the initial transfer of the device for use under this Section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

B) Any person who desires to manufacture, process, produce or initially transfer for sale or distribution industrial devices containing byproduct material for use under subsection (c)(4)(A), should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210 from NRC.

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) Exempt Material

1) Persons producing or in possession of residuals or sludge resulting from the treatment of water or sewage and containing naturally occurring radium from groundwater with concentrations of total radium (sum of radium-226 and radium-228 concentrations) less than or equal to 200 pCi/g (dry weight basis) are exempt from the licensing requirements

provided they comply with this subsection (d). Persons producing or in possession of residuals or sludge resulting from the treatment of water or sewage and containing naturally occurring radium from groundwater with concentrations of total radium greater than 200 pCi/g (dry weight basis) are not exempt and shall comply with requirements in 32 Ill. Adm. Code 330.

2) The following individuals or entities producing or in possession of residuals or sludge resulting from the treatment of water or sewage and containing naturally occurring radium from groundwater with concentrations of total radium less than or equal to 200 pCi/g (dry weight basis) must register directly with the Agency:

A) Owners and operators of facilities or plants that produce residuals or sludge resulting from the treatment of water or sewage and containing radium occurring naturally from groundwater; and

B) Owners and operators of Illinois Environmental Protection Agency (IEPA) permitted landfills if the residuals or sludge is disposed of in those landfills; and

C) Applicators who apply to agricultural lands residuals or sludge resulting from the treatment of water or sewage containing radium occurring naturally from groundwater; and

D) Any other person or entity that the Agency determines is required to register under the provisions of the Radiation Protection Act.

3) Owners and operators of facilities or plants that produce residuals or sludge resulting from the treatment of water or sewage and containing radium in concentration less than or equal to 200 pCi/g (dry weight basis) occurring naturally from groundwater will be exempt from the licensure and fee requirements of the Radiation Protection Act.

4) Residuals or sludge resulting from the treatment of water or sewage and containing naturally occurring radium from groundwater may be disposed of in accordance with the following provisions and the requirements of IEPA and the regulations of the Illinois Pollution Control Board (Title 35 of the Ill. Adm. Code: Subtitles C and G, and Part 391), as implemented by IEPA:

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A) If the level of radium in the residuals or sludge is less than or equal to 100 pCi/g (dry weight basis):

i) the residuals or sludge may be disposed of in an IEPA permitted landfill provided:

- the residuals or sludge are covered during transportation; and
- the residuals or sludge that are easily dispersible must be packaged or stabilized to prevent dispersion during transportation and/or landfill placement; and
- there is at least 10 feet of non-contaminated overburden between the residuals or sludge and grade level (at the time of landfill closure).

ii) the residuals or sludge may be used for soil conditioning purposes on agricultural crop land (e.g., corn, soybeans) provided:

- that use is in accordance with 35 Ill. Adm. Code 309.208; and
- the concentration of the radium in the residuals or sludge (dry weight basis) shall be determined by laboratory analysis; and
- the level of radium in the residuals or sludge and the application rate is such that, after the residuals or sludge is mixed with soil (for agricultural use), the cumulative increase of the total radium-226 and radium-228 combined concentration in the soil does not exceed 1.0 pCi/g (dry weight basis, an addition of 1778 microCi/acre); and
- this increased limit applies to the sum of all land applications of residuals or sludge on a specific parcel of land; and

- at no time shall the application of residuals or sludge result in the total radium concentration in the soil exceeding 3.0 pCi/g (the mean natural background as determined by the Agency of 2.0 pCi/g and the soil concentration increase limit of 1.0 pCi/g due to residuals or sludge application); and

- the landowner or an authorized agent of the landowner must acknowledge, on a form issued by the Agency, that he or she is aware that residuals or sludge containing radium is being applied to the land (this acknowledgement must be updated as landownership changes); and

- prior to using a parcel of land for the application of residuals or sludge containing radium for the first time, the generator must determine the total radium concentration in the soil using the soil sampling protocol specified below:

  - Soil sample collection shall be conducted so as to be representative of the entire sludge application site. Soil Plow Zone – one soil sample shall be collected per 8 acres of sludge application site area to a depth of 12 inches. Each soil sample shall be taken as a homogenous mixture composed of at least 10 samples randomly collected within the 8 acre area; or

  - Sampling protocols in compliance with the 24th edition of the Illinois Agronomy Handbook as published by the University of Illinois Extension Service (with sampling depth increased to 12 inches) (Pubs Plus, 1917 South Wright Street, Champaign IL 61820, 217/333-2007, PubsPlus@illinois.edu, 2009); and

  - Testing protocol specified by the Agency; and

AGENCY NOTE: The Agency will develop and provide a guidance document on residuals and sludge sampling, acceptable analysis methods and Agency reporting requirements.

- lands used for the application must have a pH equal to or greater than 6.0, have a 6-inch soil layer with a minimum clay content of at least 18% within the top 5 feet and above bedrock and the groundwater level (as determined by the County Soil Survey Book), and a 6-inch layer with an organic content of at least 12 tons/acre within the top 5 feet and above bedrock and the groundwater level (as determined by site-specific testing); and

- lands receiving residuals or sludge containing radium shall not be used for the cultivation of tobacco; and

- when the cumulative increase of the radium concentration in the soil is determined by calculation to be 0.8 pCi/g or when the total radium in soil is calculated to be 2.8 pCi/g (based on initial testing and subsequent applications of residuals or sludge containing radium), the generator must repeat the soil sampling and analysis to determine the actual total radium concentration in the soil and report the findings to the Agency; and

- when calculating the increase in radium concentration, a soil density value of 90 pounds/cubic foot and a mixing depth of 1 foot should be used.

B) If the level of radium in the residuals or sludge is greater than 100 pCi/g (dry weight basis) and less than or equal to 200 pCi/g (dry weight basis):

i) in accordance with 32 Ill. Adm. Code 340.1020, the method of disposal must be reviewed and approved by IEMA-DNS in advance; and

ii) the residuals or sludge may be disposed of in a licensed low-level radioactive waste disposal facility.

5) By June 1, 2011, all persons applying water treatment residuals or sewage treatment sludge containing radium to land in Illinois must sample fields currently being used for land application using a sampling and testing protocol specified by the Agency to determine the total radium concentration of the soil and report the findings to the Agency. Any field that has a total radium concentration greater than 3.0 pCi/g may no longer be used for the land application of water treatment residuals or sewage treatment sludge containing radium.

6) On an annual basis, each person producing water treatment residuals or sewage treatment sludge containing radium must report, in a manner specified by the Agency, the following:

A) Persons who dispose of water treatment residuals or sewage treatment sludge containing radium in a landfill must report:

i) the quantity of residuals or sludge containing radium; and

ii) the concentration of radium (in pCi/g (dry weight basis)) contained in the residuals or sludge; and

iii) the date the residuals or sludge were disposed of in a landfill; and

iv) the name and location of the landfill receiving these residuals or sludge; and

v) any additional information deemed appropriate by the Agency.

B) Persons who land apply water treatment residuals or sewage treatment sludge containing radium must report:

i) the identification, location and background radium concentrations, as determined prior to use for land application, of the field receiving the land application of residuals or sludge containing radium; and

ii) the concentration of radium in pCi/g (dry weight basis) in the residuals or sludge; and

iii) the application rate in dry tons/acre; and

iv) the date of the land application; and

v) any additional information deemed appropriate by the Agency.

7) All analysis of residuals or sludge must be conducted by a laboratory certified by the U.S. Environmental Protection Agency or the National Environmental Laboratory Accreditation Conference (NELAC) to perform radiological analysis, and concentration of radium will be determined by a method approved by the Agency.

8) Owners and operators of facilities that produce residuals or sludge that is land applied or disposed of in a landfill are not subject to the registration requirements specified in Section 4 and the fees specified in Section 13 of the Illinois Low-Level Radioactive Waste Management Act [420 ILCS 20/4 and 13] and are not subject to the reporting requirements of Access to Facilities for Treatment, Storage, or Disposal of Low-Level Radioactive Waste (32 Ill. Adm. Code 609) and Registration of Low-Level Radioactive Waste Generators (32 Ill. Adm. Code 620).

9) Owners and operators of facilities that produce residuals or sludge that is disposed of in a licensed low-level radioactive waste disposal facility are subject to the registration requirements specified in Section 4 and the fees specified in Section 13 of the Illinois Low-Level Radioactive Waste Management Act and are subject to the reporting requirements of 32 Ill. Adm. Code 609 and 620.

(Source: Amended at 39 Ill. Reg. _____, effective _____)

Section 330.220 General Licenses-Radioactive Material Other Than Source Material

~~a) Certain Devices and Equipment~~

~~1) A general license is hereby issued to transfer, receive, acquire, possess and use radioactive material incorporated in the following devices or equipment that has been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the~~

~~manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90, 340, 341 and 400 and Sections 330.40(a)(2), 330.310, 330.400 and 330.500 of this Part.~~

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

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

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

1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business and State or local government agencies to receive, acquire, possess, use or transfer, in accordance with the provisions of subsections (a~~b~~)(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~~b~~)(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 NRC ~~the U.S. Nuclear Regulatory Commission~~, an Agreement State or a Licensing State that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a former Licensing State. The devices shall have been received from a specific licensee described in this subsection (a~~b~~)(2) or through a transfer made under subsection (a~~b~~)(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~~b~~)(1)~~ of this Section~~:

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

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

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

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

C) Shall assure that testing (including testing required by subsection (a~~b~~)(3)(B)), 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 ~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State to perform such activities;

D) Shall maintain records showing compliance with the requirements of subsections (a~~b~~)(3)(B), (C) and (H) and (a~~b~~)(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~~b~~)(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~~b~~)(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~~b~~)(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~~b~~)(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 in accordance with subsection (a~~b~~)(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 nanoCi) 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~~the U.S. Nuclear Regulatory Commission~~ 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 n~~ano~~Ci) or more removable radioactive material indicates that a sealed source is leaking or contaminated; and

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

F) Shall not abandon the device containing radioactive material;

G) Shall not export the device containing radioactive material except in accordance with 10 CFR 110, published at 73 Fed. Reg. 78615, December 23, 2008, 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~~b~~)(3)(G);

ii) By transfer to another general licensee as provided by subsection (a~~b~~)(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~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State;

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

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

I) Shall furnish a written report to the Agency within 30 days after transferring, disposing of or redesignating 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) A receipt from the transferee showing the serial number of the device and the date that it was received (not applicable if exported or redesignated);

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

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

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

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~~b~~), a copy of 32 Ill. Adm. Code 310.40, 310.80, 330.310, 330.500, 340.1210, 340.1220, 340.1260 and any safety documents identified in the device labels; or

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

M) Shall furnish a report to the Agency within 30 days after transferring a device containing radioactive material as provided by subsection (a~~b~~)(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~~b~~)(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;

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

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

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

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

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

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

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

i) Devices (i.e., an electron capture detector, gauge, x-ray fluorescence analyzer, or other measuring, gauging or controlling device) containing a sealed source equal to or greater than 37 MBq (1 mCi) of radioactive material, based on the activity indicated on the label, other than strontium-90, radium-226 or polonium-210; or

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

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

ii) The name, title and phone number of the responsible individual designated by the person in accordance with subsection (a~~b~~)(3)(N) as having knowledge of and authority

to take actions to ensure compliance with the appropriate regulations and requirements;

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

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

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~~b~~)(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~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State with respect to a device identified in subsection (a~~b~~)(4)(A) is exempt from the registration requirement in subsection (a~~b~~)(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~~b~~)(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 proper operation of the on-off mechanism and indicator is not required during the storage period. However, the on-off mechanism and indicator shall be checked before the device is returned to service if the device has not been tested within the required test interval. Tests for leakage of, or contamination by, radioactive material shall be conducted during the storage interval as required by subsection (a~~b~~)(3)(B).

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~~b~~)(6)(A) shall apply.

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

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

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

b~~c~~) Luminous Safety Devices for Aircraft

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

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

B) Each device has been manufactured, assembled or imported in accordance with a specific license issued by NRC~~the U.S. Nuclear Regulatory Commission~~, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or an Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.53, published at 43 FR 6923, February 17, 1978, exclusive of subsequent amendments or editions.

2) Persons who receive, acquire, possess or use luminous safety devices pursuant to the general license in subsection (b~~e~~)(1) of this Section are exempt from the requirements of 32 Ill. Adm. Code 340 and 400, except that they shall comply with the provisions of 32 Ill. Adm. Code 340.1210 and 340.1220.

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

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

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

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

d~~e~~) Calibration and References Sources

1) A general license is hereby issued to those persons listed below to receive, acquire, possess, use and transfer, in accordance with the provisions of

subsections (d~~e~~)(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~~the U.S. Nuclear Regulatory Commission~~ that authorizes the licensee to receive, possess, use and transfer special nuclear material.

2) A general license is hereby issued to receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subsections (d~~e~~)(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~~e~~)(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~~e~~)(1) through (3) apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by NRC~~the U.S. Nuclear Regulatory Commission~~ pursuant to 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, exclusive of subsequent amendments or additions, or 70.39, published at 43 Fed. Reg. 6925, February 17, 1978, exclusive of subsequent amendments or additions, or that have been manufactured in accordance with the specifications contained in a specific license issued by the Agency, an Agreement State or a former Licensing State pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, exclusive of subsequent amendments or additions, or 70.39, published at 43 Fed. Reg. 6925, February 17, 1978, exclusive of subsequent amendments or editions.

5) The general licenses provided in subsections (d~~e~~)(1) through (3) are subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90, 340, 341 and 400 and Sections 330.310, 330.400 and 330.500 of this Part. In

addition, persons who receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

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

B) Shall not receive, possess, use or transfer such source unless the source or the storage container bears a label that includes 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~~the U.S. Nuclear Regulatory Commission~~ 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 of calibration or reference sources containing americium-241, plutonium or radium-226.

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

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

1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections (e~~f~~)(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~~f~~)(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~~f~~)(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~~f~~)(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~~f~~)(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~~f~~)(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~~the U.S. Nuclear Regulatory Commission~~ 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~~f~~)(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~~f~~)(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~~the U.S. Nuclear Regulatory Commission~~ 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~~f~~) 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~~f~~)(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) This general license is subject to the provisions of 32 Ill. Adm. Code 310 and 331.

f~~g~~) Ice Detection Devices

1) A general license is hereby issued to receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 μCi) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by NRC~~the U.S. Nuclear Regulatory Commission~~ or each device has been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

2) Persons who receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in subsection (f~~g~~)(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~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State to manufacture or service those devices; or shall dispose of the device pursuant to the provisions of 32 Ill. Adm. Code 340.1010(a);

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

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

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

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

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

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

A) Antiquities originally intended for use by the general public. For the purposes of this subsection (g~~h~~)(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 (1μCi) of radium-226. For the purposes of this subsection (g~~h~~)(1)(E), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources such as cloud chambers and spinthariscopes used in educational demonstrations, electron tubes, lightning rods, ionization sources, static eliminators or sources otherwise designated by the Agency.

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

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

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

B) Shall not abandon a product containing radium-226. The product and any radioactive material from the product shall only be disposed of in accordance with subsection (g~~h~~)(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~~h~~)(1) does not authorize the manufacture, assembly, disassembly, repair or import of a product containing radium-226, except that timepieces may be disassembled and repaired.

(Source: Amended at 39 Ill. Reg. ____, effective _____)

Section 330.240 Filing Applications for Specific Licenses

a) Application requirements:

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

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

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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 such references are clear and specific.

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

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

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

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

   A) Shall identify~~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~~Contain~~ the information identified in Section 330.280(m); or

C) Shall describe~~Describe~~, for a sealed source or device containing ~~naturally occurring or accelerator produced~~ radioactive material manufactured prior to October 23, 2015~~November 30, 2007~~, that is not registered with NRC~~the U.S. Nuclear Regulatory Commission~~ in accordance with 10 CFR 32.210 or with an Agreement State~~ or a former Licensing State~~ and for which the applicant is unable to provide the information described in Section 330.280(m)(3)~~(2)(B) or (C)~~:

i) The information required by Section 330.280(m)(3~~2~~) concerning the source and, if applicable, the device; and

ii) Sufficient additional information to demonstrate that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. The information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test; 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 supply 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 copy of a certified letter sent to the facility owner or authorized representative of the owner informing the owner that radioactive material is being or will be used or stored at the facility; or

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

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

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

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

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

1) The completeness of the application;

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

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

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

5) The applicant's history of compliance; and

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

(Source: Amended at 39 Ill. Reg. _____, effective _____)

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

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

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

A) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material and estimated concentration of the radioactive material in the product or material at the time of transfer; and

B) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

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

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

B) Name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

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

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

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

A) 5 years have passed since 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 1 year after the event has been included in a report to the Agency.

6) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Section 330.30 or 330.40(a) or the equivalent regulations of the U.S. Nuclear Regulatory Commission (10 CFR 30.14) or of an Agreement State, except in accordance with a specific license issued pursuant to this subsection (a).

b) Licensing the Distribution of Radioactive Material in Exempt Quantities

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

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

AGENCY NOTE: Subsection (o) 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~~b~~) or equivalent regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ 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 1 year a dose in excess of 10 percent of the annual limits specified in 32 Ill. Adm. Code 340.210(a); and

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

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

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

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

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

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

ii) The requirement, or lack of requirement, for testing for leakage or contamination, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of

radioactive material by radionuclide, activity and activity assay date; and

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

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.

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), published at 73 Fed. Reg. 42673, July 23, 2008, exclusive of subsequent amendments or editions 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 6 months. The interval between tests for contamination of the device or for leakage of radioactive material from the device or for both shall not exceed 3 months for devices containing sources designed to emit alpha particles and 6 months for all other devices. In the event the applicant desires that the device be required to be tested at intervals longer than the above, the applicant shall include in the application sufficient information to demonstrate that such longer intervals are justified. The information shall include a description of the performance characteristics of the device or similar devices and of design features that have a significant bearing on the probability or consequences of contamination of the device or leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material or contamination of the device, the Agency will consider information that includes, but is not limited to:

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material; and

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

3) In the event the applicant desires that the general licensee under subsection 330.220(a~~b~~), or under equivalent regulations of NRC~~the U.S.~~

~~Nuclear Regulatory Commission~~ or an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of, or contamination by, radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, is unlikely to cause that individual to receive an annual dose in excess of 10 percent of the limits specified in 32 Ill. Adm. Code 340.210(a).

4) A person licensed under this subsection (d) 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~~b~~). 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~~b~~);

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

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

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

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

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

5) A person licensed under this subsection (d) to distribute devices to generally licensed persons shall provide the information in this subsection (d)(5) to each person to whom a device is to be transferred for possession and use under a general license equivalent to Section 330.220(a~~b~~) in the regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ 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~~the U.S. Nuclear Regulatory Commission~~, exclusive of subsequent amendments or editions, or the equivalent regulations of an Agreement State. NRC~~The U.S. Nuclear Regulatory Commission~~ regulations are 10 CFR 31.5, published at 73 Fed. Reg. 42673, July 23, 2008, 10 CFR 31.2, published at 65 Fed. Reg. 79187, December 18, 2000, 10 CFR 30.51, published at 61 Fed. Reg. 24673, May 16, 1996, 10 CFR 20.2201, published at 67 Fed. Reg. 3585, January 25, 2002 and 10 CFR 20.2202, published at 63 Fed. Reg. 39483, July 23, 1998. If NRC~~the U.S. Nuclear Regulatory Commission~~ 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~~the U.S. Nuclear Regulatory Commission~~ 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 ~~the U.S. Nuclear Regulatory Commission~~ 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 device transferred after February 19, 2002, shall meet the labeling requirements of subsections (d)(1)(C), (D) and (E)~~ of this Section~~.

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

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

1) An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Section 330.220(b~~e~~) 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~~the U.S. Nuclear Regulatory Commission~~, exclusive of subsequent amendments or editions, or their equivalent. The regulations are 10 CFR 32.53, published at 77~~43~~ Fed. Reg. 4369~~36923~~, July 25, 2012~~February 17, 1978~~, 10 CFR 32.54, published at 63 Fed. Reg. 39483, July 23, 1998 and~~,~~ 10 CFR 32.55, published at 77~~39~~ Fed. Reg. 4369~~26397~~, July 25, 2012~~July 19, 1974 and 10 CFR 32.101, published at 30 Fed. Reg. 8192, June 26, 1965~~.

2) Each person licensed under this subsection (e) shall file an annual report with the Agency that shall state the total activity of tritium or promethium-147 transferred to persons generally licensed under Section 330.220(b~~e~~) or equivalent regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State. The report shall identify each general licensee by name and address, state the kinds and numbers of luminous devices

transferred and specify the activity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. 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 (3) shall also file an annual report with the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS , by an appropriate method listed in 32 Ill. Adm. Code 310.110, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under Section 330.220(b). The report must 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 must cover the year ending June 30 and must 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 must 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~~e~~). 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~~e~~) 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, published at 77 Fed. Reg. 43693, July 25, 2012~~73 Fed. Reg. 42674, July 23, 2008~~, and 10 CFR 70.39, published at 43 Fed. Reg. 6925, February 17, 1978. The applicant shall also certify that it will satisfy, and subsequently satisfies, the requirements of 10 CFR 32.58and~~,~~ 32.59~~ and 32.102~~, published at 77 Fed. Reg. 43694, July 25, 2012~~72 Fed. Reg. 55929, October 1, 2007~~, exclusive of subsequent amendments or editions.

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

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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 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.

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~~such~~ radioactive material. In the case of the mock iodine-125 reference or calibration source, the manufacturer shall state in the directions that this item shall be disposed of in compliance with 32 Ill. Adm. Code 340.1010(a) or the equivalent regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State.

h) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Section 330.220(f~~g~~) 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~~, published at 58 Fed. Reg. 67660, December 22, 1993,~~ 32.62, both published at 77~~43~~ Fed. Reg. 436946~~923~~, July 25, 2012~~February 17, 1978, and 32.103, published at 30 Fed. Reg. 9906, August 10, 1965~~, exclusive of subsequent amendments or editions, are met.

i) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals 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, packaging including maximum activity per package and shielding provided by the packaging of the radioactive material that is appropriate for safe handling and storage of radiopharmaceuticals by specific licensees; and

4) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, activity and activity assay date and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a), (b) or (c) for radioactive material specified in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010, as appropriate, or under equivalent licenses of NRC~~the U.S. Nuclear Regulatory Commission~~ 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~~such~~ reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have those~~such~~ 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~~the U.S. Nuclear Regulatory Commission~~ 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, its chemical and physical form and activity;

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

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

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

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

F) Procedures and standards for calibrating sources and devices;

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

H) Instructions for handling and storing sources or devices from the radiation safety standpoint. These instructions shall be included on a durable label attached to each source or device or attached to a permanent storage container for the source or device; provided,

that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;

3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, activity and activity assay date, radiation symbol and/or "Caution Radioactive Material", serial number, model, manufacturer name or logo, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a), (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~~the U.S. Nuclear Regulatory Commission~~ 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; ~~and~~

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

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material;

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

K) Proposed use of source; 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(d) or equivalent regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State will be approved if:

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

2) The applicant submits sufficient information relating to the design (including blueprints), manufacture (construction materials and methods), prototype testing (description of testing that will be done and the acceptance criteria), quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to assure that possession, use or transfer of the depleted uranium in the product or device will not cause any individual to receive in any period of 1 year a radiation dose in excess of 10 percent of the limits specified in 32 Ill. Adm. Code 340.210(a).

3) The applicant submits information assuring that the presence of depleted uranium for a mass-volume application in the product or device will provide a unique benefit 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~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State;

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

D) Furnish:

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

ii) A copy of the general license contained in NRC's~~the U.S. Nuclear Regulatory Commission's~~ or Agreement State's regulation equivalent to Section 330.210(d) and a copy of NRC's~~the U.S. Nuclear Regulatory Commission's~~ or Agreement State's certificate, or alternatively, furnish a

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

E) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in Section 330.210(d). 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(d) during the reporting period, the report shall so indicate;

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

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

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

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

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

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

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

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

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

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~~, importer~~ or initial distributor of a sealed source or device containing a sealed source ~~whose product is intended for use under a specific license~~ may submit a request to the Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in the NRC~~U.S. Nuclear Regulatory Commission~~ "Registry of Radioactive Sealed Sources and Devices".

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

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

~~i) Proposed uses for the sealed source;~~

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

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

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

~~v) Radiation profile of a prototype sealed source;~~

~~vi) Procedures for and results of prototype testing;~~

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

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

~~ix) Leak testing procedures; and~~

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

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

~~i) Proposed uses for the device;~~

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

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

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

~~v) Radiation profile of a prototype device;~~

~~vi) Procedures for and results of prototype testing;~~

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

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

~~ix) Leak testing procedures;~~

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

~~xi) Information about installation, service and maintenance procedures;~~

~~xii) Handling, operating and safety instructions; and~~

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

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

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

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

~~ii) The provisions of the evaluation sheet prepared by the Agency and submitted to the U.S. Nuclear Regulatory Commission for filing in the "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 (1mCi), for beta and/or gamma emitting radionuclides; or

ii) 0.37 MBq (10μCi), 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 (20Ci) 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 as 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 U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

o) 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 (o).

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~~b~~) or the equivalent regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ 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~~b~~) or the equivalent regulations of NRC~~the U.S. Nuclear Regulatory Commission~~ 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 (o). These records shall be maintained for 5 years following the recorded event.

(Source: Amended at 39 Ill. Reg. _____, effective _____)

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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 ~~[420 ILCS 40]~~, 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~~Such~~ 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, after securing full information, first:

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

2) Consents in writing to the proposed transfer, assignment or disposal.

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) ~~of this Section~~ 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)~~ of this Section~~; 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.

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

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~~the U.S. Nuclear Regulatory Commission~~, 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 ~~the~~ 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, other than sealed sources, 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 area.

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.

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~~14~~)) 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 39 Ill. Reg. _____, effective _____)