

From: [Vinson, Gibb](#)
To: [Einberg, Christian](#)
Cc: [Schneider, Kathleen](#)
Subject: FW: Illinois Draft Regulations
Date: Thursday, June 21, 2012 12:09:18 PM
Attachments: [330.220 GL Rule Roadmap.doc](#)
[330.220\(b\)\(4\)\(A\)\(i\)GL.DOC](#)
[340.1210 Theft rule.doc](#)
[ATT00002.txt](#)
[330.40 Roadmap.doc](#)
[330-40 \(2\).doc](#)
[335.5010 Pregnancy Rule RAM.DOC](#)
[335.1070 AMP.DOC](#)

Dear Mr. Einberg:

Enclosed are the draft 32 Ill. Adm. Code Parts 330.220(b)(4)(A)(i) and 330.40(c)(1)(F). These revisions were reviewed by NRC as drafts on May 30, 2006 (GL rule) and July 8, 2011, respectively. Please refer to the attached guides (330.220 GL Rule Roadmap and 330.40 Roadmap) for cross references between the NRC regulations and the Illinois rules.

In addition, we have attached two draft regulations unique to Illinois. The first, adds a pregnancy test requirement for certain thyroid patients. The Agency has been involved in several events that have occurred over the past 2 years involving the administration of I-131 to patients who were subsequently found to be pregnant at the time of administration. I-131 even in microcurie quantities can have deleterious effects on the thyroid of a fetus. The second draft regulation adds a provision for delegation of duties to authorized medical physicists (AMP). A number of hospitals recently have scheduled treatments (primarily for Y-90 microspheres) when the staff AMP's were not be available. The new provision will allow the hospital to approve AMPs from other hospitals or staff locally that may be qualified but not named on the license provided that they verify training and have signed approvals from management.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200. We request the review of these final regulations under FSME Procedure SA-201. Under this procedure, we understand that the review will be completed as soon as possible not to exceed 60 days.

Thank you for your consideration in this matter. Please send us

COMPATIBILITY COMMENTS ON ILLINOIS FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	330.220(b)(3)(D) More restrictive, no change required	§31.5(c)(4)	2001-1	B	<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.</p> <p>The Illinois rule requires records be retained for 5 years. This is more stringent than NRC rule requirement of three years.</p> <p>Illinois' rule has the essential elements of the NRC, but is more restrictive than the NRC's GL rule. As noted in the September 28, 2005 All Agreement States Letter STP-05-072, the determination on this provision will be held in abeyance until such time that the NRC completes its review and response to the Organization of Agreement State on compatibility changes for the GL rule.</p>
2	330.220(b)(3)(E) More restrictive, no change required	§31.5(c)(5)	2001-1	B	<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.</p> <p>The Illinois rule provides a time period of 5 days for filing a report with the Agency if 185 Bq or more of removable radioactive material is detected by a leak test. This is more stringent than NRC rule requirement of 30 days.</p> <p>Illinois' rule has the essential elements of the NRC, but is more restrictive than the NRC's GL rule. As noted in the September 28, 2005 All Agreement States Letter STP-05-072, the determination on this provision will be held in abeyance until such time that the NRC completes its review and response to the Organization of Agreement State on compatibility changes for the GL</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					rule.
3	330.220(b) (3)(I)(iii) More restrictive, no change required	§31.5(c)(8)	2001-1	B	<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.</p> <p>The Illinois rule requires the transferee to provide a receipt to the transferor providing the serial number of the device as well as the date that it was received. There is no requirement for this in 10 CFR 31.5(c)(8).</p> <p>Illinois' rule has the essential elements of the NRC, but is more restrictive than the NRC's GL rule. As noted in the September 28, 2005 All Agreement States Letter STP-05-072, the determination on this provision will be held in abeyance until such time that the NRC completes its review and response to the Organization of Agreement State on compatibility changes for the GL rule.</p>
4	330.220(b) (9) Attached	§31.5(c)(10)	2001-1	B	<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.</p> <p>The Illinois rule does not require reporting of radiation incidents, theft or loss of devices.</p> <p>Illinois needs to add the requirements to report radiation incidents, and the theft or loss of devices to meet the compatibility B designation assigned to 10 CFR31.5(c)(10).</p> <p>Theft and loss of devices addressed in 330.220.(b)(9) with reference to 340.1210 (attached).</p>
5	330.310(b) Attached	§31.5(c)(11)	2001-1	B	<p>Certain detecting, measuring, gauging, or controlling devices and</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>certain devices for producing light or an ionized atmosphere.</p> <p>The Illinois rule does not specifically require licensee response to written requests to provide information relating to the general license.</p> <p>Illinois needs to add a requirement to respond to written requests to provide information relating to the general license to meet the compatibility B designation assigned to 10 CFR 31.5(c)(11).</p> <p>Terms of the general license require submittal of information at request of Agency in 330.310(b) {attached}.</p>
6	330.220(b) (4)(A)(i)	§31.5(c)(13)(i)	2001-1	B	<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.</p> <p>The Illinois rule requires registration of devices based on different criteria than in 10 CFR 31.5(c)(13)(i). This approach could result in the situation in which a new device would be captured by the NRC rule, but would not be captured by the Illinois rule.</p> <p>Illinois needs to revise the registration criteria, to capture the same devices captured by the language in 10 CFR 31.5(c)(13)(i) in order to meet the compatibility designation B assigned to 10 CFR 31.5(c)(13)(i).</p> <p>330.220(b)(4)(A)(i) revised to include NRC language for “other measuring, gauging or controlling devices.”</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
7	330.900(a) & (b) More restrictive, no change required	§31.6	2001-1	B	<p>General license to install devices generally licensed in § 31.5.</p> <p>The comment on the draft rule was not addressed in the final rule. The comment was:</p> <p>Section 330.900 combines section 10 CFR 31.6, General license to install devices generally licensed in 31.5, and section 10 CFR 150.20, Recognition of Agreement State Licenses, which contains the requirements for reciprocity recognition of specific licenses through issuance of a general license.</p> <p>By combining these sections, tied together by the phrase “In addition to the provisions of subsection (a) of this section”, the Illinois rule contains additional, more restrictive provisions than are required by Section 10 CFR 31.6. The Illinois regulation requires prior notification, a 180 day reciprocity period, an additional separate report to be filed within 30 days of the end of the calendar quarter by a licensee transferring or installing a generally licensed device, and that the holder of the specific license shall furnish to each general licensee to whom he transfers or on whose premises he installs such a device a copy of the general license contained in Section 330.220(b) of this Part or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device. These requirements are more restrictive than NRC requirements given the limitations imposed by the Compatibility Category B designation.</p> <p>Illinois’ rule has the essential elements of the NRC, but is more restrictive than the NRC’s GL rule. As noted in the September 28, 2005 All Agreement States Letter STP-05-072, the determination on this provision will be held in abeyance until such time that the NRC completes its review and response to the Organization of Agreement State on compatibility changes for the GL rule. the Petition for Rulemaking and request for change in compatibility.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	330.900(c) More restrictive, no change required	§31.6	2001-1	B	<p>General license to install devices generally licensed in § 31.5.</p> <p>The comment on the draft rule was not addressed in the final rule. The comment was:</p> <p>Illinois states that they have the right to “withdraw, limit, or qualify its acceptance of” any specific license issued by NRC or another state, or any product distributed pursuant to that license, if the “Agency determines that had that person been licensed in Illinois by the Agency, the license would have been subject to action under Section 330.500 (Modification and Revocation of Licenses) or 310.90 (Impounding). NRC has no specific license revocation provisions for GL servicers and installers in 10 CFR 31.6 The Illinois requirements are more restrictive than NRC requirements given the limitations imposed by the Compatibility Category B designation.</p> <p>Illinois’ rule has the essential elements of the NRC, but is more restrictive than the NRC’s GL rule. As noted in the September 28, 2005 All Agreement States Letter STP-05-072, the determination on this provision will be held in abeyance until such time that the NRC completes its review and response to the Organization of Agreement State on compatibility changes for the GL rule.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	330.40 (c) (1)(F)	§30.15	2007-2	B	<p>Certain items containing byproduct material Illinois' regulation omits the language "Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires".</p> <p>NRC language added to 330.40 (c) (1)(F)</p> <p>Illinois needs to add the above language in order to meet the Compatibility Category B designation assigned to 10 CFR 30.15 (a)(7).</p> <p>COMMENT STANDS from NRC letter dated April 15, 2010. Illinois revised 330.40(c)(3)(A), which is equivalent to 10 CFR 30.20, to incorporate the requirements of 10 CFR 30.15. However, as written, the revision does not address the requirements of 30.15(a)(7) and changes the meaning of the 10 CFR 30.20 equivalent provision. Both provisions are designated Compatibility Category B. New comment generated. See Comment 2 below.</p>
2	333.40 (c)(3)(A)	30.20	N/A	B	<p>Gas and Aerosol Detectors Containing Radioactive Material Illinois revised the language in 330.40(c)(3)(A): Gas and Aerosol Detectors Containing Radioactive Material, which is the equivalent to 10 CFR 30.20, to incorporate the provisions in 10 CFR 30.15. As revised, this provision addresses only americium-241 and not the broader category of radioactive material.</p> <p>333.40 (c)(3)(A) amended to include <u>all gas and aerosol detectors not just smoke detectors.</u></p>

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

PART 330
LICENSING OF RADIOACTIVE MATERIAL

SUBPART A: GENERAL PROVISIONS

Section

- 330.10 Purpose and Scope
- 330.15 Incorporations by Reference
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Section

- 330.200 Types of Licenses
- 330.210 General Licenses – Source Material
- 330.220 General Licenses – Radioactive Material Other Than Source Material

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Section

- 330.240 Filing Applications for Specific Licenses
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- 330.260 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Materials
- 330.270 Special Requirements for Specific Licenses of Broad Scope
- 330.280 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material
- 330.290 Requirements for Emergency Plans
- 330.300 Issuance of Specific Licenses
- 330.310 Terms and Conditions of Specific and General Licenses
- 330.320 Renewal Requirements for Specific Licenses
- 330.325 Termination Requirements for Specific Licenses and Locations of Use
- 330.330 Renewal of Licenses (Repealed)
- 330.340 Amendment of Licenses at Request of Licensee
- 330.350 Agency Action on Application to Renew or Amend
- 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

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Section

- 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)

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 27, 2008; amended at 33 Ill. Reg. 4918, effective March 23, 2009; amended at 35 Ill. Reg. 2931, effective February 7, 2011.

Section 330.40 License Exemption – Radioactive Materials Other Than Source Material

a) Exempt Concentrations

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

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 of this Part, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this subsection (b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or an Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.18 or 32.21, or by the Agency pursuant to Section 330.280(b), 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, 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 receives, possesses, uses, transfers, owns or acquires the following products:

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

- A) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified

radiation dose rate:

- i) 925 MBq (25 mCi) of tritium per timepiece;
 - ii) 185 MBq (5 mCi) of tritium per hand;
 - iii) 555 MBq (15 mCi) of tritium per dial (bezels when used shall be considered as part of the dial);
 - iv) 3.7 MBq (100 microCi) of promethium-147 per watch or 7.4 MBq (200 microCi) of promethium-147 per any other timepiece;
 - v) 740 kBq (20 microCi) of promethium-147 per watch hand or 1.48 MBq (40 microCi) of promethium-147 per other timepiece hand;
 - vi) 2.22 MBq (60 microCi) of promethium-147 per watch dial or 4.44 MBq (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 per square centimeter of absorber: for wrist watches, 1 microGy (100 microrad) per hour at 10 centimeters from any surface; for pocket watches, 1 microGy (100 microrad) per hour at 1 centimeter from any surface; for any other timepiece, 2 microGy (200 microrad) per hour at 10 centimeters from any surface; or
 - viii) 37 kBq (1 microCi) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.
- 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) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.

AGENCY NOTE: For purposes of subsection (c)(1)(D), "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 ten exempt quantities. For purposes of this requirement, an instrument's sources may contain one or more radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B, provided that the sum of such 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.

2) Self-Luminous Products Containing Radioactive Material

- A) Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance

with a specific license, issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this subsection (c)(2)(A) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments. The U. S. Nuclear Regulatory Commission shall make this determination of exemption.

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

3) Gas and Aerosol Detectors Containing Radioactive Material

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

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

- B) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State or a former Licensing State shall be considered exempt under subsection (c)(3)(A), 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.

(Source: Amended at 35 Ill. Reg. 2931, effective February 7, 2011)

Section 330.220 General Licenses – Radioactive Material Other Than Source Material

a) Certain Devices and Equipment

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

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

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

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

- 1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business and State or local government agencies to receive, acquire, possess, use or transfer, in accordance with the provisions of subsections (b)(2) through (9), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
- 2) The general license provided by subsection (b)(1) applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to Section 330.280(d) or in accordance with the specifications contained in an equivalent specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a

Licensing State that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a former Licensing State. The devices shall have been received from a specific licensee described in this subsection (b)(2) or through a transfer made under subsection (b)(3)(L).

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

- 3) Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license described in subsection (b)(1) of this Section:
 - A) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained on the device and shall comply with all instructions and precautions provided by such labels;
 - B) Shall assure that the device is tested for leakage of, or contamination by, radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified on the device labels; however:
 - i) A device containing only krypton need not be tested for leakage of, or contamination by, radioactive material; and
 - ii) A device containing only tritium or not more than 3.7 MBq (100 microCi) of other beta and/or gamma emitting material or 370 kBq (10 microCi) of alpha emitting material or a device held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
 - C) Shall assure that testing (including testing required by subsection (b)(3)(B)), installation, servicing and removal from installation involving the radioactive material, its shielding or containment is performed:
 - i) In accordance with the instructions provided by the labels; or

- ii) By a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;
- D) Shall maintain records showing compliance with the requirements of subsections (b)(3)(B), (C) and (H) and (b)(6)(B). The records shall show the results of tests. The records shall also show the dates of performance of, and the names of persons performing, physical inventories, testing, installation, servicing and removal from installation of radioactive material or its shielding or containment. Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license provided by subsection (b)(1) shall retain these records as follows:
- i) A record of a test of an on-off mechanism and indicator or a test for leakage or contamination performed in accordance with subsection (b)(3)(B) 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 (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 (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 (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, 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 nanoCi) 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 nanoCi) 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 (b)(3)(G);

- ii) By transfer to another general licensee as provided by subsection (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 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, the U.S. Nuclear Regulatory Commission or an Agreement State; or
 - v) As approved under subsection (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 (b)(3)(O) of this Section provides information about redesignation of administrative control over a device.
- J) Shall maintain a record of the transfer or disposal of the device as required by subsection (b)(3)(D)(iii);
- K) Shall obtain written approval from the Agency before transferring the device to a transferee not identified in subsections (b)(3)(H)(i) through (iv);
- 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 (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 (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 (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 (b)(3)(A) so that the device is labeled in compliance with 32 Ill. Adm. Code 340.910; however, the manufacturer, model number and serial number shall be retained;
 - iii) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and
 - iv) Reports the new designation as required by subsection (b)(3)(I).
- 4) Any person who receives, acquires, possesses or uses a device identified in subsection (b)(4)(A) shall register with the Agency in accordance with subsection (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 (b)(1):
 - i) **Devices (i.e., an electron capture detector, gauge, ~~or~~ x-ray fluorescence analyzer, or other measuring, gauging or controlling devices) 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;**
 - ii) A device containing a sealed source equal to or greater than 3.7 MBq (100 μ Ci) of strontium-90 or radium-226; or
 - iii) ~~A static control or measuring device containing a sealed source equal to or greater than 37 MBq (1 mCi) of radioactive material other than polonium-210 or radium-226;~~

- B) A person shall register with the Agency no later than 30 days after receiving a device identified in subsection (b)(4)(A). Registration information shall be in a format prescribed by the Agency and furnished in accordance with subsection (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 (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 (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 (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 (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 the U.S. Nuclear Regulatory Commission or an Agreement State with respect to a device identified in subsection (b)(4)(A) is exempt from the registration requirement in subsection (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 (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 (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 (b)(6)(A) shall apply.

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

- 7) Failure of any person to comply with the requirements of this subsection (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 (b)(1) does not authorize the manufacture of devices containing radioactive material.
- 9) The general license described in subsection (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 330.500 of this Part. Any person who receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license described in subsection (b)(1) of this Section is exempt from the requirements of 32 Ill. Adm. Code 400 and 340 except for the Sections of 32 Ill. Adm. Code 340 specifically identified in subsections (b)(3)(E) and (b)(9) of this Section.

c) Luminous Safety Devices for Aircraft

- 1) A general license is hereby issued to receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:
 - A) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300 mCi) of promethium-147; and
 - B) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or an Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.53, published at 43 FR 6923, February 17, 1978, exclusive of subsequent amendments or editions.
- 2) Persons who receive, acquire, possess or use luminous safety devices pursuant to the general license in subsection (c)(1) of this Section are exempt from the requirements of 32 Ill. Adm. Code 340 and 400, except that they shall comply with the provisions of 32 Ill. Adm. Code 340.1210 and 340.1220.
- 3) This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium-147.

- 4) This general license does not authorize the receipt, acquisition, possession or use of promethium-147 contained in instrument dials.
 - 5) This general license is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90 and 341 and Sections 330.310, 330.400 and 330.500 of this Part.
- d) **Ownership of Radioactive Material.** A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.
- e) **Calibration and References Sources**
- 1) A general license is hereby issued to those persons listed below to receive, acquire, possess, use and transfer, in accordance with the provisions of subsections (e)(4) and (5), americium-241 in the form of calibration or reference sources:
 - A) Any person who holds a specific license issued by the Agency that authorizes the licensee to receive, possess, use and transfer radioactive material; and
 - B) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission that authorizes the licensee to receive, possess, use and transfer special nuclear material.
 - 2) A general license is hereby issued to receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subsections (e)(4) and (5) to any person who holds a specific license issued by the Agency that authorizes the licensee to receive, possess, use and transfer radioactive material.
 - 3) A general license is hereby issued to receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of subsections (e)(4) and (5) to any person who holds a specific license issued by the Agency that authorizes the licensee to receive, possess, use and transfer radioactive material.
 - 4) The general licenses in subsections (e)(1) through (3) apply only to calibration or reference sources that have been manufactured in

accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, exclusive of subsequent amendments or additions, or 70.39, published at 43 Fed. Reg. 6925, February 17, 1978, exclusive of subsequent amendments or additions, or that have been manufactured in accordance with the specifications contained in a specific license issued by the Agency, an Agreement State or a former Licensing State pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57, published at 73 Fed. Reg. 42674, July 23, 2008, exclusive of subsequent amendments or additions, or 70.39, published at 43 Fed. Reg. 6925, February 17, 1978, exclusive of subsequent amendments or editions.

- 5) The general licenses provided in subsections (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 μ Ci) of americium-241, 185 kBq (5 μ Ci) of plutonium or 185 kBq (5 μ Ci) 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, 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.
- f) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

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

- 1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections (f)(2) through (6), 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 μ Ci) each.

- B) Cobalt-57, in units not exceeding 370 kBq (10 μ Ci) each.
 - C) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 μ Ci) each.
 - D) Iodine-125, in units not exceeding 370 kBq (10 μ Ci) 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 μ Ci) each.
 - G) Iron-59, in units not exceeding 740 kBq (20 μ Ci) each.
 - H) Selenium-75, in units not exceeding 370 kBq (10 μ Ci) each.
- 2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (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 (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 (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 (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 μ Ci).
 - B) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - C) The general licensee shall use the radioactive material only for the uses authorized by subsection (f)(1).
 - D) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 - E) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in subsection (f)(1)(E) as required by 32 Ill. Adm. Code 340.1010(a).
- 4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to subsection (f)(1):
 - 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 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 subsection (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 (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.
- 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 μ Ci) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

- 2) Persons who receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in subsection (g)(1):
 - A) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage or contamination and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service those devices; or shall dispose of the device pursuant to the provisions of 32 Ill. Adm. Code 340.1010(a);
 - B) Shall assure that all labels affixed to the device at the time of receipt, and that bear a statement that prohibits removal of the labels, are maintained on the device; and
 - C) Are exempt from the requirements of 32 Ill. Adm. Code 340 and 400 except that such persons shall comply with the provisions of 32 Ill. Adm. Code 340.1010(a), 340.1210, 340.1220 and 340.1260.
- 3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.
- 4) This general license is subject to the provisions of 32 Ill. Adm. Code 310.40 through 310.90 and 341 and Sections 330.310, 330.400 and 330.500 of this Part.

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

- 1) A general license is hereby issued to any person to acquire, receive, possess, use or transfer, in accordance with the provisions of this subsection (h), radium-226 contained in the following products manufactured prior to November 30, 2007:
 - A) Antiquities originally intended for use by the general public. For the purposes of this subsection (h)(1)(A), antiquities means products originally intended for use by the general public 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 μ Ci), nonintact timepieces and timepiece hands and dials no longer installed in timepieces;
 - C) Luminous items installed in air, marine or land vehicles;
 - D) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time; and
 - E) Small radium sources containing no more than 37 kBq (1 μ Ci) of radium-226. For the purposes of this subsection (h)(1)(E), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources such as cloud chambers and spinthariscopes used in educational demonstrations, electron tubes, lightning rods, ionization sources, static eliminators or sources otherwise designated by the Agency.
- 2) Any person who acquires, receives, possesses, uses or transfers radioactive material under the general license in subsection (h)(1) is exempt from the provisions of 32 Ill. Adm. Code 340 and 400 to the extent that the receipt, possession, use or transfer of radioactive material is within the terms of the general license. This exemption does not apply to any person specifically licensed under this Part.
- 3) Any person who acquires, receives, possesses, uses or transfers radioactive material in accordance with the general license in subsection (h)(1):
- A) Shall notify the Agency within 30 days if there is any indication of possible damage to a product that could result in loss of radioactive material. The report shall provide a brief description of the event and the remedial action taken;
 - B) Shall not abandon a product containing radium-226. The product and any radioactive material from the product shall only be disposed of in accordance with subsection (h)(3)(D);
 - C) Shall not export a product containing radium-226, except in accordance with 10 CFR 110, published at 73 Fed. Reg. 78615, December 23, 2008, exclusive of subsequent amendments or editions; and

- D) Shall dispose of a product containing radium-226 only in accordance with 32 Ill. Adm. Code 340.1010(a), or by transfer to a person specifically licensed under this Part to receive the radium-226 in the product, or as otherwise approved by the Agency in writing.
- 4) The general license in subsection (h)(1) does not authorize the manufacture, assembly, disassembly, repair or import of a product containing radium-226, except that timepieces may be disassembled and repaired.

(Source: Amended at 35 Ill. Reg. 2931, effective February 7, 2011)

Section 335.1070 Authorities and Responsibilities for the Authorized Medical Physicist

- a) In addition to the radiation protection program requirements of 32 Ill. Adm. Code 340.110, a licensee's management shall approve in writing: any individual before allowing that individual to work as an Authorized Medical Physicist.
- b) A licensee may permit an authorized medical physicist qualified under Sections 335.9150 and 335.9160 of this Part, to function as an Authorized Medical Physicist designee and to perform the functions of an Authorized Medical Physicist specified in Sections 335.2140, 335.7070, 335.7080, . 335.8020, 335.8040, 335.8050, 335.8090, 335.8100, 335.8160, 335.8170, 335.8190, 335.8200 and 335.8220 if the licensee takes the actions in subsections (a) and (d).
- c) A licensee may simultaneously appoint more than one temporary Authorized Medical Physicist in accordance with subsection (b) of this Section, if needed to ensure that the licensee has a temporary Authorized Medical Physicist that satisfies the requirements to be an Authorized Medical Physicist for each of the different types of uses of radioactive material permitted by the license.
- d) The licensee shall retain a copy of each Authorized Medical Physicist agreement to be responsible for implementing the approved procedures and regulatory requirements as required by subsection (b) of this Section, for the duration of the license. The records shall include the signature of the Authorized Medical Physicist and the licensee's management.

TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION
PART 335 MEDICAL USE OF RADIOACTIVE MATERIAL
SECTION 335.5010 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED

Section 335.5010 Use of Unsealed Radioactive Material for Which a Written Directive is Required

- a) _____ A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:
- a)i) Obtained from a person specified in Section 335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements;
 - b)ii) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 335.9040 or 335.9050 of this Part, or an individual under the supervision of either as specified in Section 335.1050 of this Part;
 - c)iii) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a protocol accepted by FDA; or
 - d)iv) Prepared by the licensee for use in research in accordance with an application or a protocol accepted by FDA.
- b) _____ Prior to any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131 to a female capable of childbirth, the licensee shall conduct a test and obtain those results to determine pregnancy. If, because of the patient's condition, the delay caused by conducting such a test would jeopardize the patient's health, the test may be forgone provided such is noted by the authorized user on the written directive required by Section 1110 of this Part. The written directive must also indicate that the patient was informed of the decision to forego the test or the reason for omission of the patient notification. Nothing in this section relieves the licensee from meeting the requirements of 32 Ill. Adm. Code 335.1100 regarding reporting of exposures to a fetus/embryo.



c) Records of the test in subsection (b) of this section shall contain the patient's name/identification number if one has been assigned, the type of test performed, results of the test, the date of the test and the date the results became available if different from the test date and the identity of the licensee's staff administering the test.

(source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

Section 340.1210 Reports of Stolen, Lost or Missing Sources of Radiation

- a) Telephone Reports. Each licensee or registrant shall report to the Agency by telephone each stolen, lost or missing source of radiation immediately after its absence becomes known to the licensee or registrant. This requirement does not apply to sources of radiation that are not required to be licensed or registered.
- b) Written Reports. Each licensee or registrant required to make a report pursuant to subsection (a) of this Section shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:
 - 1) A description of the source of radiation involved, including for radioactive material, the kind, quantity and chemical and physical form; and, for radiation machines, the type of unit, the manufacturer, model and serial number;
 - 2) A description of the circumstances under which the loss or theft occurred;
 - 3) A statement of disposition, or probable disposition, of the source of radiation involved;
 - 4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
 - 5) Actions that have been taken, or will be taken, to recover the source of radiation; and
 - 6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the theft or loss of sources of radiation.
- c) Subsequent to filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.
- d) The licensee or registrant shall prepare any report filed with the Agency pursuant to this Section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(Source: Amended at 29 Ill. Reg. 20841, effective December 16, 2005)

confirmation that these rules have been received and accepted for review. If you have any questions, please feel free to contact me at (217) 785-9947.

Regards, Gibb

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