ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Licensing of Radioactive Material

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

3)

Section Number:	Proposed Action:
330.30	Amendment
330.210	Amendment
330.280	Amendment

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

5) A Complete Description of the Subjects and Issues Involved: The proposed amendments establish new requirements for distributors of source material to persons exempt from the regulations or for use under a general license. In addition, the proposed amendments reduce certain possession limits and modify use requirements for general licensees to align the requirements with current health and safety standards. Finally, the proposed amendment revise, clarify or delete certain exemptions to make the exemptions more current with today's market and more risk informed. These changes will affect manufacturers and distributors of products and materials containing source material and future users of some products used under exemptions from licensing and under a general license. The products include certain glass lenses, heat resistant ceramics, ceramic tableware, certain halide lamps, counterweights and certain metals.

These proposed amendments are required for compatibility, category B, C and D with the U.S. Nuclear Regulatory Commission's (USNRC) changes to 10 CFR 40 pursuant to RATS ID 2013-2 (78 FR 32310, published May 29, 2013). The regulations are required to be adopted by the state of Illinois no later than August 27, 2016.

Section 31 of the Radiation Protection Act of 1990 [420 ILCS 40/31] provides that the Agency is **EXEMPT** from rulemaking procedures in the Illinois Administrative Procedure Act when regulations that are identical in substance are necessary to implement, secure or maintain federal authorization for a program. After consideration of comments from the appropriate federal agency, the Agency may adopt the verbatim text of the laws, regulations or orders as necessary and appropriate for authorization or maintenance of the program. The USNRC has reviewed these proposed amendments and has provided comments to the Agency. Changes based on USNRC's review have been incorporated where necessary. Because this rulemaking is not subject to the Illinois Administrative Procedure Act, and in accordance with Section 31, this rulemaking will become effective following the first notice period immediately upon filing for adoption

with the Secretary of State, or at a date required or authorized by the relevant federal laws, regulations or orders as stated in the notice of the rulemaking, and shall be published in the Illinois Register.

6) Any published studies or reports, along with the sources of underlying data, that were used when composing this rulemaking, in accordance with 1 Ill Adm. Code 100.355:

No, this rule is being amended solely on the basis of compatibility with the USNRC's changes to 10 CFR Part 40 pursuant to RATS ID #2013-2 (78 FR 32310, published May 29, 2013).

7) Will this rulemaking replace an emergency rule currently in effect? No

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

9) Does this rulemaking contain incorporations by reference? Yes

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives:

The proposed rulemaking is not expected to require local governments to establish, expand or modify their activities in such a way as to necessitate additional expenditures from local revenues.

12) Time, Place and Manner in which interested persons may comment on this rulemaking: Comments on this proposed rulemaking may be submitted in writing for a period of 45 days following publication of this notice. The Agency will consider fully all written comments on this proposed rulemaking submitted during the 45 day comment period. Comments should be submitted to:

Traci Burton
Paralegal Assistant
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, Illinois 62704

217-785-9860
Fax: 217-524-3698

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities or not-for-profit corporations affected: The Agency does not believe small businesses, small municipalities or not-for-profit corporations will be affected.

B) Reporting, bookkeeping or other procedures required for compliance: Radioactive material licensees will be required to maintain manufacturing records, inventories, contamination control records and records of transfers/disposals of material.

C) Types of professional skills necessary for compliance: Generally, these proposed amendments will only affect existing facilities with radiation safety experts on staff. Additional clerical skills are required for accountability and reporting of certain benchmarks.

14) Regulatory Agenda on which this rulemaking was summarized: January 2016 (It was incorrectly labeled under 32 Ill. Adm. Code 310.)

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

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

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

PART 330
LICENSING OF RADIOACTIVE MATERIAL

SUBPART A: GENERAL PROVISIONS

SUBPART B: TYPES OF LICENSES

SUBPART C: SPECIFIC AND GENERAL LICENSES

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

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 13, 2008; amended at 33 Ill. Reg. 4918, effective March 23, 2009; amended at 35 Ill. Reg. 2931, effective February 7, 2011; amended at 35 Ill. Reg. 3969, effective February 28, 2011; emergency amendment at 35 Ill. Reg. 5654, effective March 21, 2011, for a maximum of 150 days; amended at 35 Ill. Reg. 9009, effective June 2, 2011; amended at 37 Ill. Reg. 5789, effective April 16, 2013; amended at 37 Ill. Reg. 7960, effective May 31, 2013; amended at 38 Ill. Reg. 21451, effective October 31, 2014; amended at 39 Ill. Reg. 11905, effective August 17, 2015; amended at 39 Ill. Reg. 15706, effective November 24, 2015; amended at 40 Ill. Reg. _____ effective _____.

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

Section 330.30 License Exemption − Source Material

a) Any person is exempt from this Part to the extent that the~~such~~ person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution or alloy.

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

c) Any person is exempt from the requirements for a license set forth in section 62 of the Atomic Energy Act of 1954, as amended, this Part and 32 Ill. Adm. Code 340 and 400~~from this Part~~ to the extent that the~~such~~ person receives, possesses, uses or transfers:

1) Any quantities of thorium contained in:

A) Incandescent gas mantles;

B) Vacuum tubes;

C) Welding rods;

D) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;

E) Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium;

F) Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these; or

G) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

2) Source material contained in the following products:

A) Glazed ceramic tableware, manufactured before August 27, 2016, provided that the glaze contains not more than 20 percent by weight source material;

B) Piezoelectric ceramic containing not more than two percent by weight source material;

C) Glassware containing not more than two percent by weight source material or, for glassware manufactured before August 27, 2016, not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; and

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

3) Photographic film, negatives and prints containing uranium or thorium.

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

5) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of those~~such~~ counterweights, provided that:

~~A~~) ~~The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or the Atomic Energy Commission authorizing distribution by the licensee pursuant to 10 CFR 40.13(c)(5)(i), as in effect on June 30, 1969, exclusive of subsequent amendments or editions;~~

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

AGENCY NOTE: The requirement specified in subsection (c)(5)(B) above does not need to be met by counterweights manufactured prior to December 31, 1969; provided that thesuch counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend, "CAUTION − RADIOACTIVE MATERIAL − URANIUM", as previously required by 10 CFR 40.13(c)(5)(ii), as in effect on June 30, 1969, exclusive of subsequent amendments or editions.

BC) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and

AGENCY NOTE: The requirement specified in subsectionssubsection (c)(5)(A) and (B)(C) above does not need to be met by counterweights manufactured prior to December 31, 1969; provided that thesuch counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend, "CAUTION − RADIOACTIVE MATERIAL − URANIUM", as previously required by 10 CFR 40.13(c)(5)(ii), as in effect on June 30, 1969, exclusive of subsequent amendments or editions.

CD) This exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or covering.

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

A) The shipping container is conspicuously and legibly impressed with the legend, "CAUTION − RADIOACTIVE SHIELDING − URANIUM"; and

B) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 3.2 millimeters (⅛ inch).

7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than ten percent by weight thorium or uranium or, for lenses manufactured before August 27, 2016, ~~does not contain more than~~ 30 percent by weight of thorium and that this exemption shall not be deemed to authorize either:

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

B) The receipt, possession, use or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

~~8)~~ ~~Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (5 nCi) of uranium; or~~

8~~9~~) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

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

B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

9) No person may initially transfer for sale or distribution a product containing source material to persons exempt under subsection (c) unless authorized by an NRC license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

A) Persons initially distributing source material in products covered by the exemptions in subsection (c) before August 27, 2016, without specific authorization may continue such distribution for

one year beyond this date. Initial distribution may also be continued until NRC takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

B) Persons authorized to manufacture, process or produce these materials or products containing source material under a specific license issued by the Agency and persons who import finished products or parts, for sale or distribution, must be authorized by an NRC license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of 10 CFR 19, 20 and 40.32(b) and (c).

d) The exemptions in subsection (c) ~~above~~ do not authorize the manufacture of any of the products described.

e) Any licensee is exempt from the requirements of this Part to the extent that its activities are subject to the requirements of 32 Ill. Adm. Code 601, except as specifically provided for in 32 Ill. Adm. Code 601.

(Source: Amended at 40 Ill. Reg. _____, effective _____.)

Section 330.210 General Licenses – Source Material

a) A general license is hereby issued authorizing commercial and industrial firms; research, educational and medical institutions; and, federal, State and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial or operational purposes in the following forms and quantities:

1) No more than 1.5 kilograms (3.3 pounds) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use and transfer source material under this subsection may not receive more than a total of 7 kilograms (15.4 pounds) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these

limits as of August 27, 2016, may continue to possess up to 7 kilograms (15.4 pounds) of uranium and thorium at any one time for one year beyond this date, or until the Agency takes final action on a pending application submitted on or before August 27, 2017, for a specific license for that material; and receive up to 70 kilograms (154 pounds) of uranium or thorium in any one calendar year until December 31, 2017, or until the Agency takes final action on a pending application submitted on or before August 27, 2017, for a specific license for that material; and

2) No more than:

A) a total of 7 kilograms (15.4 pounds) of uranium and thorium at any one time. A person authorized to possess, use and transfer source material under subsection (a) may not receive more than a total of 70 kilograms (154 pounds) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under subsection (a)(2)(A) unless it is accounted for under the limits of subsection (a)(1); or

B) No more than 7 kilograms (15.4 pounds) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kilograms (154 pounds) of uranium from drinking water during a calendar year under subsection (a); or

C) No more than 7 kilograms (15.4 pounds) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use and transfer source material under subsection (a) may not receive more than a total of 70 kilograms (154 pounds) of source material in any one calendar year. ~~a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local government agencies to use, possess and transfer not more than 6.82 kilograms (15 pounds) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use, possess or transfer source material, pursuant to this general license, may not receive more than a total of 68.2 kilograms (150 pounds) of source material in any 1 calendar year.~~

b) Any person who receives, possesses, uses or transfers source material in accordance with the general license in subsection (a):

1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license;

2) Shall not abandon such source material. Source material may be disposed of as follows:

A) A cumulative total of 0.5 kilograms (1.1 pounds) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of subsection (b)(2)(A) is exempt from the requirements to obtain a license under this Part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under Subchapter b; or

B) In accordance with 32 Ill. Adm. Code 340.1010;

3) Is subject to the provisions in 32 Ill. Adm. Code 310, 330.310(a) through (c), 330.400, 330.500 and 340.1220(a) through (d);

4) Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days after the date of the request, or other time specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Agency, a written justification for the request; and

5) Shall not export such source material except in accordance with 10 CFR 110. ~~b) Persons who receive, possess, use or transfer source material pursuant to the general license issued in subsection (a) are exempt from the provisions of 32 Ill. Adm. Code 340 and 400 to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to~~

~~apply to any such person who is also in possession of source material under a specific license issued pursuant to this Part.~~

c) Any person who receives, possesses, uses or transfers source material in accordance with subsection (a) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in Section 330.325(b)(1)(ii).

d) Any person who receives, possesses, uses or transfers source material in accordance with the general license granted in subsection (a) is exempt from the provisions of 32 Ill. Adm. Code 340 and 400 to the extent that such receipt, possession, use and transfer are within the terms of this general license, except that such person shall comply with the provisions of Section 330.325(b)(1)(B)(ii) and 32 Ill. Adm. Code 340.1010 to the extent necessary to meet the provisions of subsections (b)(2) and (c) of this Section. However, this exemption does not apply to any person who also holds a specific license issued under Subchapter b.

e) No person may initially transfer or distribute source material to persons generally licensed under subsection (a)(1) or (2) unless authorized by a specific license issued in accordance with Section 330.280(o). This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by subsection (a) before August 27, 2016, without specific authorization, may continue for one year beyond this date. Distribution may also be continued until the Agency takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2017.

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

~~g~~d) Depleted Uranium in Industrial Products and Devices

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

1) A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with this subsection (g)~~the provisions of subsections (gd)(2) through (5)~~, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2) The general license in subsection (gd)(1) applies only to industrial products or devices that~~which~~ have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to Section 330.280(l) ~~of this Part~~ or in accordance with a specific license issued to the manufacturer by NRC~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State that authorizes manufacture of the products or devices for distribution to persons generally licensed by NRC~~the U.S. Nuclear Regulatory Commission~~ or an Agreement State.

3) Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by subsection (gd)(1) shall:

A) File the form~~,~~ "Registration Certificate − Use of Depleted Uranium Under General License," with the Agency~~Department~~. The form shall be submitted within 30 days after the first receipt or acquisition of ~~such~~ depleted uranium. The registrant shall furnish the following information on the form ~~"Registration Certificate − Use of Depleted Uranium Under General License," the following information~~:

i) Name and address of the registrant;

ii) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subsection (gd)(1) and designed to prevent transfer of the~~such~~ depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

iii) Name and/or title, address and telephone number of the individual duly authorized to act for and on behalf of the

registrant in supervising the procedures identified in subsection (gd)(3)(A)(ii).

B) Report in writing to the Agency any changes in information furnished by the registrant in the form., ~~"Registration Certificate – Use of Depleted Uranium Under General License."~~ The report shall be submitted within 30 days after the effective date of the~~such~~ change.

4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by subsection (gd)(1):

A) Shall not introduce the~~such~~ depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

B) Shall not abandon the~~such~~ depleted uranium;

C) Shall transfer or dispose of the~~such~~ depleted uranium only ~~by transfer~~ in accordance with ~~the provisions of~~ Section 330.400 ~~of this Part~~. When~~In the case where~~ the transferee receives the depleted uranium pursuant to the general license established by subsection (gd)(1), the transferor shall furnish the transferee a copy of this Part and a copy of the form, "Registration Certificate – Use of Depleted Uranium Under General License". When~~In the case where~~ the transferee receives the depleted uranium pursuant to a general license contained in NRC's~~the U.S. Nuclear Regulatory Commission's~~ regulation 10 CFR 40.25(a) or Agreement State's regulation equivalent to subsection (gd)(1), the transferor shall furnish the transferee a copy of this Part and a copy of the form~~,~~ ~~"Registration Certificate – Use of Depleted Uranium Under General License",~~ accompanied by 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 this Part;

D) Within 30 days after any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium through that~~pursuant to such~~ transfer; and

E) Shall not export thesuch depleted uranium except in accordance with a license issued by NRCthe U.S. Nuclear Regulatory Commission pursuant to 10 CFR 110.

5) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by subsection (gd)(1) is exempt from the requirements of 32 Ill. Adm. Code 340 and 400 with respect to the depleted uranium covered by that general license.

(Source: Amended at 40 Ill. Reg. _____, effective _____.)

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

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

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

A) The applicant submits:

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

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

iii) method of introduction;,

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

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

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

vii) estimated concentration of the radioactive material in the product or material at the time of transfer; and

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

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

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

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

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

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

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

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

B) The licensee has:

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

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

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

5) The licensee shall maintain the record of a transfer for a period of one~~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 NRC~~the U.S. Nuclear Regulatory Commission~~ (10 CFR 30.14) or of an Agreement State, except in accordance with a specific license issued under~~pursuant to~~ this subsection (a).

b) Licensing the Distribution of Radioactive Material in Exempt Quantities

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

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

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

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

AGENCY NOTE: Subsection (pd) describes requirements for radioactive material transfer reports and records.

1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Section 330.220(a) or equivalent regulations of NRC or an Agreement State will be approved if:

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

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

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

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

iii) Under accident conditions such as fire and explosion associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation

dose or dose commitment in excess of the following organ doses:

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

Hands and forearms; feet and ankles or localized areas of skin averaged over areas no larger than one~~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 contains~~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 on~~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 the~~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~~State~~ with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

OR

CAUTION – RADIOACTIVE MATERIAL
Name of Manufacturer or Distributor

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

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

E) Each device meeting the criteria of 10 CFR 31.5(c)(13)(i)~~, 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 six~~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 three~~3~~ months for devices containing sources designed to emit alpha particles and six~~6~~ months for all other devices. In the event the applicant desires that the device be required to be tested at longer intervals ~~longer than the above~~, the applicant shall include in the application sufficient information to demonstrate that those~~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 Section~~subsection~~ 330.220(a), or under equivalent regulations of NRC or an Agreement State, be authorized to install the device, collect the sample

to be analyzed by a specific licensee for leakage of, or contamination by, radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities and bases for the~~such~~ estimates. The submitted information shall demonstrate that performance of the~~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). This information shall be provided before a device is transferred. In the case of a transfer through an intermediate person, the information shall be provided to the intended user prior to transfer to the intermediate person. The required information is:

A) A copy of Section 330.220(a);

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

B) A copy of 32 Ill. Adm. Code 310.40, 330.310 and 340.1210, 340.1220 and 340.1260;

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

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

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

5) A person licensed under this subsection (d) to distribute devices to generally licensed persons shall provide the information in this subsection (d)(5) to each person to whom a device is to be transferred for possession and use under a general license equivalent to Section 330.220(a) in the regulations of NRC or an Agreement State. This information shall be provided before a device is transferred. In the case of a transfer through an intermediate person, the information shall be provided to the intended user prior to transfer to the intermediate person. The required information is:

A) A copy of the following regulations of NRC~~, exclusive of subsequent amendments or editions,~~ or the equivalent regulations of an Agreement State. NRC 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 regulations are provided to a prospective general licensee in lieu of applicable Agreement State regulations, they shall be accompanied by a note explaining that use of the device is regulated by the Agreement State;

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

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

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

D) A statement of the policies of NRC and most Agreement States to take escalated enforcement action for improper disposal; and

E) The name or title, address and phone number of the contact at NRC or Agreement State regulatory agency from whom additional information may be obtained.

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

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

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

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

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

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

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

2) Each person licensed under this subsection (e) shall file an annual report with the Agency that shall state the total activity of tritium or promethium-147 transferred to persons generally licensed under Section 330.220(b) or equivalent regulations of NRC or an Agreement State. The report shall identify each general licensee by name and address, state the kinds and numbers of luminous devices transferred and specify the activity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers have been made to a particular Agreement State during the

reporting period, this information must be reported to the responsible Agreement State agency upon request of the Agency.

3) Each person licensed under this subsection (e) shall also file an annual report with the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, U.S. Nuclear Regulatory Commission, Washington DC 20555by 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). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Section 330.220(d) will be approved if:

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

2) The applicant satisfies the requirements of 10 CFR 32.57~~, published at~~ (77 Fed. Reg. 43693, July 25, 2012) 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 32.58 and 32.59, ~~published at~~ (77 Fed. Reg. 43694, July 25, 2012)~~, 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), or equivalent regulations of NRC or an Agreement State, will be approved if:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

> This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of NRC~~the U.S. Nuclear Regulatory Commission~~ or of a state with which NRC~~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 radioactive material. In the case of the mock iodine-125 reference or calibration source, the manufacturer shall state in the directions that this item shall be disposed of in compliance with 32 Ill. Adm. Code 340.1010(a) or the equivalent regulations of NRC or an Agreement State.

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

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

2) The criteria of 10 CFR 32.61 and 32.62~~, both published at~~ (77 Fed. Reg. 43694, July 25, 2012)~~, exclusive of subsequent amendments or editions,~~ are met.

i) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses.

1) 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 vial, syringe, generator or other container of the radioactive drug; and the ~~package and~~ shielding provided by the packaging to show it ~~of the radioactive material that~~ is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees ~~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 that~~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 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

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

AGENCY NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of those reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have those reagent kits approved by the Agency for use by persons licensed pursuant to Section 330.260(a), (b) or (c) for generators or reagent kits specified in 32 Ill. Adm. Code 335.4010 may submit the pertinent information specified in this subsection (j).

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

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

2) The applicant submits evidence that:

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

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

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

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

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

A) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

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

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

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

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

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

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

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

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

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

F) Procedures and standards for calibrating sources and devices;

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

H) Instructions for handling and storing sources or devices from the radiation safety standpoint. These instructions shall be included on a durable label attached to each source or device or attached to a permanent storage container for the source or device; provided, that instructions that~~which~~ are too lengthy for the~~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~~Caution Radioactive Material~~", serial number, model, manufacturer name or logo, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a), (b) or (c) and 32 Ill. Adm. Code 335.2040, 335.2140, 335.6010, 335.7010 and 335.8010 or under equivalent licenses of NRC or an Agreement State, provided that the labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;

4) In the event the applicant desires that the source or device be required to be tested for leakage of, or contamination by, radioactive material at intervals longer than 6 months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of radioactive contamination or leakage of radioactive material from the source;

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

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material;

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

K) Proposed use of source; and

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

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

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

2) The applicant submits sufficient information relating to the design (including blueprints), manufacture (construction materials and methods), prototype testing (description of testing that will be done and the acceptance criteria), quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to assure that possession, use or transfer of the depleted uranium in the product or device will not cause any individual to receive in any period of one~~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 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(gd) 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(gd); or

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

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

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

i) To NRC all transfers of industrial products or devices to persons for use under NRC general license in 10 CFR 40.25;

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

iii) To NRC if no transfers have been made by the licensees during the reporting period;

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

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

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

1) An application for license to manufacture or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive those~~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 or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in the NRC "Registry of Radioactive Sealed Sources and Devices".

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

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

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

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

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

B) The provisions of the registration certificate.

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

A) Calibration and reference sources containing no more than:

i) 37 MBq (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 NRC~~the U.S. Nuclear Regulatory Commission~~ or of a state with which NRC~~the Commission~~ has entered into an agreement for the exercise of regulatory authority.

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

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

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

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

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

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

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

a) A copy of Sections 330.210 and 330.400; and

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

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

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

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

ii) For each general licensee under Section 330.210 to whom greater than 50 grams (0.11 pounds) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form and quantity of source material transferred; and

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

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

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

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

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

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

6) Each person licensed under this subsection (o) shall maintain all information that supports the reports required by subsection (o)(5)

concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Agreement State agency or NRC.

pe) 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 (pe).

1) The person shall report:

A) To the Agency and to the responsible regulatory agency all transfers of devices to persons for use under the general license in Section 330.220(a) or the equivalent regulations of NRC or an Agreement State;

B) To the Agency and to the responsible regulatory agency all receipts of devices from persons generally licensed under Section 330.220(a) or the equivalent regulations of NRC or an Agreement State;

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

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

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

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

A) The identity of the general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted, along with information on the actual location of use;

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

C) The date of transfer;

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

E) The radionuclide and activity contained in the device.

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

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

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

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

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

(Source: Amended at 40 Ill. Reg. _____, effective _____)