ILLINOIS EMERGENCY MANAGEMENT AGENCY
AND OFFICE OF HOMELAND SECURITY

NOTICE OF PROPOSED AMENDMENT

TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY AND OFFICE OF HOMELAND SECURITY
SUBCHAPTER b: RADIATION PROTECTION

PART 330
LICENSING OF RADIOACTIVE MATERIAL

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(Repealed)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. 12971, effective August 25, 2016; amended at 46 Ill. Reg. 866, effective December 21, 2021; amended at 47 Ill. Reg. _____, effective _____.

Section 330.20 Definitions

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

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

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

medical use or the practice of nuclear pharmacy issued by a U.S. Nuclear Regulatory Commission master material licensee.

"*Authorized nuclear pharmacist"* means a pharmacist who:

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

Is identified as an authorized nuclear pharmacist on:

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

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

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

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

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

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

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

radionuclide production facility within the consortium must be located at an educational institution or a medical facility.

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

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

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

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

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

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(Source: Amended at 48 Ill. Reg. _____, effective _____)

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

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

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

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

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

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

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

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

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

A) Compliant with the U.S. Food and Drug Administration (FDA) registration requirements as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR Part 207;

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

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

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

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

3) The applicant submits information showing that:

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

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

4) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees;

5) The applicant commits to the following labeling requirements:

A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The

label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label;

6) A licensee described by subsection (c)(2)(C) or (D):

A) May prepare radioactive drugs for medical use, as defined in 32 Ill. Adm. Code 335.20, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in subsections (c)(6)(B) and (C), or an individual under the supervision of an authorized nuclear pharmacist as specified in subsection (c)(15).

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

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

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

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

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C) May designate a pharmacist (as defined in 32 Ill. Adm. Code 310) as an authorized nuclear pharmacist if:

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

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

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

i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State as specified in subsection (c)(18)(A); or

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

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

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

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

E) Shall provide notification to the Agency no later than 30 days after an authorized user or an authorized nuclear pharmacist permanently discontinues performance of duties under the license or has a name change;

7) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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

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

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

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

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

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

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

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

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

13) A licensee such as a nuclear pharmacy that is authorized to distribute radiopharmaceuticals shall ensure that radiopharmaceuticals are dispensed only under the prescription of a physician who is authorized by 32 Ill. Adm. Code 335 to use the radiopharmaceuticals. The licensee shall verify that the physician is authorized to receive the prescribed radiopharmaceutical prior to transfer;

AGENCY NOTE: In accordance with 32 Ill. Adm. Code 335.40(b), licensees authorized for medical use of radiopharmaceuticals may permit work as an authorized user in limited circumstances without first obtaining

an amendment. Therefore, possession of the recipient's latest radioactive material license may not list all authorized users.

14) A licensee shall apply for and shall receive a license amendment before it receives, prepares or uses radioactive material for a type of use that is permitted under this Part but that is not authorized on the licensee's current license issued under this Part;

15) Individuals Under Supervision of an Authorized Nuclear Pharmacist

A) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist as allowed by 32 Ill. Adm. Code 335.30(b)(2) shall:

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

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

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

16) Authority and responsibilities for the radiation protection program.

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

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

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

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

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

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

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

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

i) Identify radiation safety problems;

ii) Initiate, recommend or provide corrective actions;

iii) Stop unsafe operations; and

iv) Verify implementation of corrective actions.

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

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

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

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

appointing the Associate Radiation Safety Officer signed by the licensee's management.

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

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

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

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

- Pass an examination administered by diplomates of the specialty board that evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry; or

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

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

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

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

B) Has completed a structured educational program consisting of:

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

ii) 1 year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory

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

- Shipping, receiving and performing related radiation surveys;
- Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- Securing and controlling radioactive material;
- Using administrative controls to avoid mistakes in the administration of radioactive material;
- Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- Using emergency procedures to control radioactive material; and
- Disposing of radioactive material; and

iii) Written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is

seeking approval as a Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in subsections (B)(i), (B)(ii) and (D), and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or Associate Radiation Safety Officer for a nuclear pharmacy license; or

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

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

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

iii) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation

Safety Officer and the authorized user on the same new nuclear pharmacy license.

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

18) Training for an authorized nuclear pharmacist. Except as provided in subsection (c)(19), the licensee shall require the authorized nuclear pharmacist to be a State of Illinois licensed pharmacist who:

A) Is certified as a nuclear pharmacist by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. To be recognized, a specialty board shall require a candidate for certification to:

i) Graduate from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council of Pharmaceutical Education) ~~(ACPE)~~ or pass the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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

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

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

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

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

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

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

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

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

Commission or Agreement State broad scope licensee or master materials license permit or by a master materials license permittee of broad scope on or before January 14, 2022 need not comply with the training requirements in subsection (c)(18);

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

A) An individual identified on an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2022, need not comply with the training requirements of 32 Ill. Adm. Code 335.9010, 335.9150, or subsection (c)(18), respectively, except the Radiation Safety Officers identified in this subsection shall meet the training requirements in 32 Ill. Adm. Code 335.9010(e) or 335.9150(d) for any material or uses for which they were not authorized prior to this date.

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

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

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

21) Recentness of Training. The training and experience specified in subsections (c)(17) and (c)(18) shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed;

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

23) Licensing the production of PET radioactive drugs for noncommercial distribution within a consortium. An application from a medical facility or

educational institution to produce PET radioactive drugs for noncommercial distribution within its consortium for use under 32 Ill. Adm. Code 335 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall include:

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

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

C) If the applicant is a nuclear pharmacy:

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

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

D) The information required by subsection (c)(4) for each PET radioactive drug to be noncommercially distributed within the consortium; and

E) Verification that the applicant is in compliance with:

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

ii) The labeling requirements of subsection (c)(5) for each PET radioactive drug transport radiation shield and each syringe, vial or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

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

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

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

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

e) Use of Radioactive Materials in Wireline Service Operations and Subsurface Tracer Studies. A specific license for use of radioactive material in wireline operations shall be issued only if the applicant has met the requirements of this Part and 32 Ill. Adm. Code 351.

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

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 330.270 Special Requirements for Specific Licenses of Broad Scope

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

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

a) The different types of broad scope licenses are:

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

2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of Appendix D. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I of Appendix D for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II of Appendix D. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column II of Appendix D for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

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

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

2) The applicant has engaged in a reasonable number of activities involving

the use of radioactive material;

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

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

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

ii) To establish a quorum and to conduct business, at least one-half of the Committee membership must be in attendance and shall include, at a minimum, the management's representative, an authorized user and the Radiation Safety Officer. However, no more than once per year, the Radiation Safety Officer's designee may substitute for the Radiation Safety Officer, provided the designee has been given a written report. The report shall include all information necessary for that meeting, such as the minutes of the previous Committee meeting and reports by the Radiation Safety Officer. Reports by the Radiation Safety Officer shall include reports of investigations and information necessary for the reviews. To maintain membership on the Committee, a member must attend at least one-half of the meetings held in any year.

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

- The date of the meeting;

- Members in attendance;

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

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

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

C) The establishment of appropriate administrative procedures to assure:

i) Control of procurement and use of radioactive material;

ii) Completion of safety evaluations of proposed uses of radioactive material that take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

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

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

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

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

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

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

B) The establishment of appropriate administrative procedures to assure:

i) Control of procurement and use of radioactive material;

ii) Completion of safety evaluations of proposed uses of radioactive material that take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

iii) Review, approval and recording by the Radiation Safety Officer of safety evaluations of proposed uses prepared in accordance with subsection (c)(2)(B)(ii) prior to use of the radioactive material.

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

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

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

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

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

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

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

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

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

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

C) Conduct activities for which a specific license issued by the Agency under Section 330.260 or 330.280 is required; or

D) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

2) Each Type A specific license of broad scope issued under this Part shall be

subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's Radiation Safety Committee.

3) Each Type B specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's Radiation Safety Officer.

4) Each Type C specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of subsection (d)(2).

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

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

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

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

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

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

g) A licensee possessing a Type A specific license of broad scope for use described in Section 330.260(c)(2)(C) or 330.260(c)(2)(D) is exempt from the provisions of Sections 330.260(c)(6)(B)(ii), 330.340(b)(4), 330.260(c)(6)(D), and 330.260(c)(6)(E).

(Source: Amended at 48 Ill. Reg. _____, effective _____)

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Section 330.400 Transfer of Material

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

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

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

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

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

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

5) As otherwise authorized by the Agency in writing.

c) Before transferring radioactive material to a specific licensee of the Agency, the NRC, or an Agreement State or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the radionuclide, form and activity of radioactive material to be transferred.

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

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

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

3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the radionuclide, form and activity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

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

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

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

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 330.950 Nationally Tracked Sources

a) Each licensee who manufactures a nationally tracked source after April 1, 2008 shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

b) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

1) The name, address and license number of the reporting licensee;

2) The name of the individual preparing the report;

3) The manufacturer, model and serial number of the source;

4) The radioactive material in the source;

5) The initial source strength in becquerels (curies) at the time of manufacture; and

6) The manufacture date of the source.

c) Each licensee who transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

1) The name, address and license number of the reporting licensee;

2) The name of the individual preparing the report;

3) The name and license number of the recipient facility and the shipping address;

4) The manufacturer, model and serial number of the source or, if not available, other information to uniquely identify the source;

5) The radioactive material in the source;

6) The initial or current source strength in becquerels (curies);

7) The date for which the source strength is reported;

8) The shipping date;

9) The estimated arrival date; and

10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

d) Each licensee who receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

1) The name, address and license number of the reporting licensee;

2) The name of the individual preparing the report;

3) The name, address and license number of the person who provided the source;

4) The manufacturer, model and serial number of the source or, if not available, other information to uniquely identify the source;

5) The radioactive material in the source;

6) The initial or current source strength in becquerels (curies);

7) The date for which the source strength is reported;

8) The date of receipt; and

9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

e) Each licensee who disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

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1) The name, address and license number of the reporting licensee;

2) The name of the individual preparing the report;

3) The manufacturer, model and serial number of the source or, if not available, other information to uniquely identify the source;

4) The radioactive material in the source;

5) The initial or current source strength in becquerels (curies);

6) The date for which the source strength is reported; and

7) The disassembly date of the source.

f) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report shall include the following information:

1) The name, address and license number of the reporting licensee;

2) The name of the individual preparing the report;

3) The waste manifest number;

4) The container identification with the nationally tracked source;

5) The date of disposal; and

6) The method of disposal.

g) The reports discussed in subsections (b) through (f) shall be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports shall be submitted to the National Source Tracking System by using:

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1) The on-line National Source Tracking System;

2) Electronic submission in a computer-readable format;

3) Facsimile;

4) Mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

5) Telephone with follow up by facsimile or mail.

h) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days after discovery of the error or missed transaction. Such errors may be detected by a variety of methods, such as administrative reviews or physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation shall be conducted during January of each year. The reconciliation process shall include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subsections (b) through (f). By January 31 of each year, each licensee shall submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

~~i) Each licensee who possesses Category 1 and/or Category 2 nationally tracked sources shall report its initial inventory of Category 1 and/or Category 2 nationally tracked sources to the National Source Tracking System in accordance with the schedule specified in 10 CFR 20.2207(h) of the U.S. Nuclear Regulatory Commission regulations. The information may be submitted by using any of the methods identified by subsection (g)(1) through (g)(4). The initial inventory report must include the following information:~~

~~1) The name, address and license number of the reporting licensee;~~

~~2) The name of the individual preparing the report;~~

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~~3) The manufacturer, model and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~

~~4) The radioactive material in the sealed source;~~

~~5) The initial or current source strength in becquerels (curies); and~~

~~6) The date for which the source strength is reported;~~

~~AGENCY NOTE: Reports and inventories must be sent to the U.S. Nuclear Regulatory Commission National Source Tracking System and not to the Illinois Emergency Management Agency, Division of Nuclear Safety. If the U.S. Nuclear Regulatory Commission does not have the National Source Tracking System established and available to receive incoming reports, then the licensee shall make such reports at a later date specified by the U.S. Nuclear Regulatory Commission on its website.~~

(Source: Added at 48 Ill. Reg. _____, effective _____)