Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION
PART 330 LICENSING OF RADIOACTIVE MATERIAL
SECTION 330.260 SPECIAL REQUIREMENTS FOR ISSUANCE OF CERTAIN SPECIFIC LICENSES FOR RADIOACTIVE MATERIALS

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) Registered with the U.S. Food and Drug Administration (FDA) 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 207.20(a);

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 satisfies the following labeling requirements:

A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the

words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label;

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

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

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

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

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

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

C) May designate a pharmacist (as defined in Section 330.20) 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) Prior to allowing the individual to work as an authorized nuclear pharmacist under subsections (c)(6)(B)(i) and (iii), shall provide to the Agency a copy of the individual's State of Illinois pharmacist license and:

i) A copy of the 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) with the written attestation signed by a preceptor as required by subsection (c)(18)(B)(iii); or

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

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

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

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

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

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

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

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

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

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

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

10) The licensee shall adhere to the concentration limits and other requirements of 32 Ill. Adm. Code 335.4020;

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 dispense radiopharmaceuticals shall ensure that radiopharmaceuticals are dispensed only under the prescription of a physician who is authorized in a specific license to use the radiopharmaceuticals. The licensee shall maintain a copy of the recipient's radioactive material license and shall verify that the physician is authorized to receive the prescribed radiopharmaceutical prior to transfer;

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 who is an authorized user 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 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) A licensee shall apply for and shall receive a license amendment identifying an authorized nuclear pharmacist as defined in Section 330.20 of this Part before it allows the individual to work as an authorized nuclear pharmacist. The individual shall meet the requirements in subsections (c)(18) and (21). An experienced nuclear pharmacist shall meet the requirements in subsection (c)(20);

17) The licensee shall require an individual fulfilling the responsibilities of Radiation Safety Officer at a nuclear pharmacy to be an individual who:

A) Is certified by a specialty board whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in subsections (c)(17)(B)(i) and (ii). To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:

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;

ii) 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

iii) Pass an examination administered by diplomate 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

B) Has met the requirements of subsections (c)(17)(B)(i) and (ii) and completed a structured educational program consisting of:

i) 200 hours of didactic 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, Agreement State or former Licensing 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 involving shipping, receiving and performing related radiation monitoring;

iii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, instruments used to measure radionuclides and survey meters;

iv) Securing and controlling radioactive material;

v) Using administrative controls to avoid mistakes in the administration of radioactive material;

vi) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

vii) Using emergency procedures to control radioactive material; and

viii) Disposing of radioactive material; or

C) Is an authorized nuclear pharmacist identified on the licensee's license, meets the requirements of subsections (c)(17)(B)(i) and (ii) and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and

D) Obtained written attestation, signed by a preceptor authorized nuclear pharmacist Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (c)(17)(B)(ii) and (c)(17)(A)(i) first and second points or subsection (c)(17)(A)(ii) or (iii) and has achieved a level of radiation safety knowledge sufficient to function independently as an authorized nuclear pharmacist Radiation Safety Officer; and

E) Trained 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 or authorized nuclear pharmacist, as appropriate, who is authorized for the types of use for which the licensee is seeking approval;

18) Before a licensee permits an individual to work as an authorized nuclear pharmacist under his or her license, the licensee shall require the individual 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 and who meets the requirements in subsection (c)(18)(B)(iii). To be recognized, a specialty board shall require a candidate for certification to:

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

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

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

iv) Pass an examination in nuclear pharmacy, administered by diplomate of the specialty board, that evaluates knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes and research and development; or

B) Has completed 700 hours in a structured educational program consisting of both didactic training in radiation physics and instrumentation or radiation protection with:

i) 200 hours of didactic 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) Written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (c)(18)(B) or subsections (c)(18)(A)(i) through (iii) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist;

AGENCY NOTE: The requirements in this subsection (c)(18) do not apply to an individual who meets the requirements of subsection (c)(19).

19) An individual identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or former Licensing 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;

20) Training for Experienced Nuclear Pharmacist. A State of Illinois licensed pharmacist who has completed a structured educational program as specified in subsection (c)(18)(B) before October 24, 2007 and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement and recentness of training to qualify as an authorized nuclear pharmacist;

21) Recentness of Training. The training and experience specified in subsection (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)(3) 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.

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 35 Ill. Reg. 2931, effective February 7, 2011)