August 12, 2008

James G. Luehman, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Luehman,

Enclosed is a copy of the final regulations 32 Ill. Adm. Code 330 and 335. These regulations are being implemented to maintain compatibility with the U.S. Nuclear Regulatory Commission's regulations 10 CFR 32 and 35. These regulations implement new training requirements for pharmacists and physicians. The regulations are identified by line-in/line-out text and correspond to the following equivalent amendments to NRC's regulations.

| **Rats ID** | **Title** | **State Section** |
|---|---|---|
| 2005-2/2006-1 | Part 32/35 | 330.260(c)(17-18) - final<br>335.30 - final<br>335 Subpart J - final<br>330.260(c)(2-6) - proposed<br>330.280(k) - proposed |

We have also incorporated your comments on these regulations as detailed in letter dated March 12, 2008 with a few exceptions. We did not incorporate Comment 3. One of the objectives of this rulemaking was to eliminate outdated terms including 'Teletherapy Physicist.' The Agency has been using the term 'Medical Physicist' for over 10 years on our licenses. We also have no units of this type in Illinois any longer and do not intend to authorize these.

Comments 10 and 11 for medical manufacturing operations did not make it into this version of Part 330. Our legislative review panel would not allow us to open these sections up at that time. However, we have proposed a new draft to correct this. Please find these attached as the proposed 330.260(c)(2-6) and 330.280(k).

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (217) 785-9928 or via e-mail at Gibb.Vinson@illinois.gov.

Sincerely,

Charles G. Vinson, Head
Radioactive Materials Section
Illinois Emergency Management Agency

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

1) Heading of the Part: Medical Use of Radioactive Material

2) Code Citation: 32 Ill. Adm. Code 335

3)

| Section Number: | Proposed Action: |
|---|---|
| 335.20 | Amendment |
| 335.30 | Amendment |
| 335.2080 | Amendment |
| 335.3010 | Amendment |
| 335.4010 | Amendment |
| 335.9010 | Amendment |
| 335.9030 | Amendment |
| 335.9040 | Amendment |
| 335.9050 | Amendment |
| 335.9060 | Amendment |
| 335.9070 | Amendment |
| 335.9080 | New |
| 335.9100 | Amendment |
| 335.9120 | Amendment |
| 335.9140 | Amendment |
| 335.9150 | Amendment |
| 335.9160 | Amendment |
| 335.9190 | Amendment |
| 335.Appendix A | Repealed |

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

5) Effective Date of Amendments:

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

7) Does this rulemaking contain incorporations by reference? Yes

8) A copy of the adopted amendments, including any material incorporated by reference is on file at the Agency's headquarters located at 1035 Outer Park Drive, Springfield, Illinois and is available for public inspection.

9) Notice of Proposal Published in the Illinois Register: 32 Ill. Reg. 3503; March 14, 2008

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10) Has JCAR issued a Statement of Objections to these Amendments? No

11) Differences between proposal and final version:

a. Several grammatical and stylistic changes were made in accordance with JCAR's recommendation.
b. Sec. 335.9010 – reformatted structure resulting in labeling change.
c. Sec. 335.9010(e) (originally published in the Register as 9010(c)) – changed "subsection (a) or (b)" to "subsection (f) and (a)(1)(A) and (a)(1)(B) or (a)(2)(A) and (a)(2)(B) or meets subsections (c) or (d)".
d. Sec. 335.9030(a)(1) – changed "subsections (c)(1) and (c)(2)" to "paragraphs (c)(1) and (c)(2)(F)".
e. Sec. 335.9140(a) – changed "subsection (b) of this Section" to "subsection (b)(3) and (b)(4) of this Section"
f. Sec. 335.9140(b)(3) – corrected a subsection misreference from "and (c)" to "and (b)(4)".
g. Sec. 335.9150(b)(2) – changed "or (b)(1) and (c)" to "or (b)~~(1)~~ and (c)".

12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreement letter issued by JCAR? Section 31 of the Radiation Protection Act exempts from the IAPA's general rulemaking requirements IEMA rulemakings that are identical in substance to NRC rules and necessary to implement, secure or maintain federal authorization for an IEMA program.

13) Will these amendments replace an emergency rule currently in effect? No

14) Are there any amendments pending on this Part? No

15) Summary and Purpose of amendments: These regulations provide for training of authorized user physicians for medical use of radionuclides. These changes are considered Compatibility A, B and C or a Health and Safety standard by the U.S. Nuclear Regulatory Commission (NRC) and must be adopted essentially verbatim by the Agency in order to maintain it's "Agreement State" status. This rulemaking will ensure compatibility with the NRC's 10 CFR 20, 30, 23, 35, 40 and 70 regulations currently in place for medical use of radioactive materials. The changes are mandated in 70 FR 16336 (RATS ID #2005-2) and 71 FR 15005 (RATS ID #2006-1). Agreement States such as Illinois are required to have these regulations in place by April 29, 2008 and March 27, 2009.

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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 NRC has reviewed the proposed amendments and the text has been revised to incorporate its suggested changes.

16) Information and questions regarding these adopted amendments shall be directed to:

Louise Michels
Staff Attorney
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, Illinois 62704
(217) 785-9876

The full text of the Adopted Amendment begins on the next page:

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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

PART 335
MEDICAL USE OF RADIOACTIVE MATERIAL

SUBPART A: GENERAL INFORMATION

Section
335.10 Purpose and Scope
335.15 Incorporations by Reference
335.20 Definitions
335.30 License Required
335.40 License Amendments
335.50 Written Directives (Repealed)
335.60 Provisions for the Protection of Human Research Subjects

SUBPART B: GENERAL ADMINISTRATIVE REQUIREMENTS

Section
335.1010 ALARA Program (Repealed)
335.1020 Radiation Safety Officer (Repealed)
335.1030 Radiation Safety Committee (Repealed)
335.1040 Authorities and Responsibilities for the Radiation Protection Program
335.1050 Supervision
335.1060 Authorized User and Visiting Authorized User
335.1070 Mobile Nuclear Medicine Service Administrative Requirements (Repealed)
335.1080 Report and Notification of a Medical Event
335.1090 Materials Authorized for Medical Use (Repealed)
335.1100 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child
335.1110 Written Directives
335.1120 Procedures for Administrations Requiring a Written Directive

SUBPART C: GENERAL TECHNICAL REQUIREMENTS

Section
335.2010 Possession, Use and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material

SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

335.9120 Training for Ophthalmic Use of Strontium-90
335.9130 Training for Use of Sealed Sources for Diagnosis
335.9140 Training for Use of Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units
335.9150 Training for Authorized Medical Physicist
335.9160 Training for Experienced Radiation Safety Officer, Authorized Medical Physicist or Authorized User
335.9170 Physician Training in a 3-Month Program (Repealed)
335.9180 Recentness of Training
335.9190 Resolution of Conflicting Requirements During Transition Period

335.APPENDIX A List of Specialty Board Certifications Accepted by the Agency Until October 24, 2007

AUTHORITY: Implementing and authorized by Section 10 of the Radiation Protection Act of 1990 [420 ILCS 40/10].

SOURCE: Adopted at 15 Ill. Reg. 10763, effective July 15, 1991; emergency amendment at 17 Ill. Reg. 9099, effective June 8, 1993, for a maximum of 150 days; amended at 18 Ill. Reg. 7308, effective May 2, 1994; emergency amendment at 26 Ill. Reg. 4434, effective March 8, 2002, for a maximum of 150 days; amended at 26 Ill. Reg. 10517, effective July 1, 2002; amended at 27 Ill. Reg. 10057, effective June 30, 2003; recodified from the Department of Nuclear Safety to the Illinois Emergency Management Agency at 27 Ill. Reg. 13641; amended at 30 Ill. Reg. 9029, effective April 28, 2006; amended at 32 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL INFORMATION

**Section 335.20 Definitions**

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using or storing radioactive material.

"Authorized user" means a physician, dentist or podiatrist who meets the requirements in Subpart J of this Part or is identified as being authorized to use radioactive material on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by a U.S. Nuclear Regulatory Commission, Agreement State or Licensing 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.

"Authorized medical physicist" means an individual who meets the requirements in Sections 335.9150(a) and 335.9180 of this Part; ~~or Section 335.9190(b) of this Part until October 24, 2007;~~ or is identified as an authorized medical physicist or teletherapy physicist on a specific medical use license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by a U.S. Nuclear Regulatory Commission, Agreement State or Licensing 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.

"Case" means the performance of a clinical procedure on a patient.

"Classroom and laboratory training" means planned instruction outlined in a syllabus and offered by an individual or organization. It is comprised of lectures, demonstrations, hands-on laboratory exercises and tests.

"Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with Section 335.2120 of this Part.

"Clinical procedure" means a method of using radioactive material for patient care in which the material or its radiation is administered to the patient. A specific clinical procedure specifies, either explicitly or in context, the indication for the procedure, the purpose (diagnosis or therapy), the radionuclide and its chemical and physical form, the dosage or dose and method of administration and patient follow-up. Diagnostic clinical procedures also include the method of collecting raw data, manipulating the data and interpreting the final results, which may be images, graphs or numbers.

"Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice dentistry.

"Gamma stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

"High dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Intravascular brachytherapy" means a type of brachytherapy in which the brachytherapy sources are placed into blood vessels at the point where the dose is prescribed for the treatment of in-stent restenosis.

"Low dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

"Management" means the chief executive officer or other individual having the authority to manage or administer the licensee's activities, or those individuals' delegates.

"Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"Medical event" means an event that meets the criteria in Section 335.1080 of this Part.

"Medical institution" means:

An organization, other than a medical clinic, private medical practice or mobile nuclear medicine service, that holds a specific license issued by the Agency and that practices more than two medical disciplines; or

A medical clinic, private practice or mobile nuclear medicine service that holds a specific license issued by the Agency and is authorized under Section 335.2140, 335.5010 (for therapy procedures only), 335.7010 or 335.8010 of this Part to use radioactive material.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Medium dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Mobile medical service" means the transportation of radioactive material to, and its medical use at, the client's address.

"Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"Physically present" means within audible range and in such proximity that immediate assistance can be given if required.

"Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice podiatry.

"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 or a Radiation Safety Officer.

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

in a written directive; or

in accordance with the directions of the authorized user for procedures pursuant to Sections 335.3010 and 335.4010 of this Part.

"Prescribed dose" means:

for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

for teletherapy, the total dose and dose per fraction as documented in the written directive;

for manual brachytherapy and intravascular brachytherapy, either the total dose or the total source strength and exposure time, as documented in the written directive; or

for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Pulsed dose rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose rate" range, and:

is approximately one-tenth of the activity of typical high dose rate remote afterloader sources; and

is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

"Radiation Safety Officer" means an individual who:

meets the requirements in Sections 335.9010, 335.9160 and 335.9180 of this Part; or

~~meets the requirements in Section 335.9190(b) of this Part until October 24, 2007; or~~

is identified as a Radiation Safety Officer on:

a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; or

a medical use permit issued by the Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State broad scope licensee or master material license permit or by a master material license permittee of broad scope Commission master material licensee.

"Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

"Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Type of use" means use of radioactive material under Sections 335.2140, 335.3010, 335.4010, 335.5010, 335.6010, 335.7010 or 335.8010 of this Part.

"Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Visiting authorized user" means a temporary (i.e., less than 60 days each year) authorized user who is not identified on the license of the licensee being visited and who has been approved by the Radiation Safety Committee in accordance with Section 335.1060(b) of this Part.

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Section 335.1110 of this Part.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.30 License Required**

a) A person may only use ~~manufacture, produce, acquire, receive, possess, prepare, use, or transfer~~ radioactive material or a radioactive sealed source for medical use that is: ~~only in accordance with a specific license issued by the Agency in accordance with 32 Ill. Adm. Code 330 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or as allowed in subsection (b)(1) or (b)(2) of this Section.~~

1) manufactured , produced, acquired, received, possessed, prepared or transferred in accordance with a specific license issued by the Agency in accordance with 32 Ill. Adm. Code 330.260(c), 330.280(i-k) or 330.280(n) or the equivalent regulations of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or as allowed in subsections (b)(1) or (b)(2) of this Section; or,

2) noncommercially transferred as sealed sources or devices from a facility licensed in accordance with this Part.

b) A specific license is not needed for an individual who:

1) Receives, possesses, uses or transfers radioactive material in accordance with this Part under the supervision of an authorized user as provided in Section 335.1050 of this Part, unless prohibited by license condition; or

2) Prepares unsealed radioactive material for medical use in accordance with this Part under the supervision of an authorized nuclear pharmacist or authorized user as provided in Section 335.1050 of this Part, unless prohibited by license condition.

c) Notwithstanding the distribution requirements in this Section, the licensee may receive, possess, and use naturally-occurring or accelerator-produced radioactive material (NARM) specifically authorized by the license and distributed by a supplier located in a non-Licensing State.

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(Source: Amended at 32 Ill. Reg. _____, effective _____)

SUBPART C: GENERAL TECHNICAL REQUIREMENTS

**Section 335.2080 Monitoring for Contamination and Ambient Radiation Dose Rate**

a) In addition to the monitoring required by 32 Ill. Adm. Code 340, the licensee shall monitor with a radiation detection survey instrument capable of detecting dose rates over the range 1 μSv ~~mSv~~ (100 μrem ~~mrem~~) per hour to 500 μSv ~~mSv~~ (50 mrem) per hour all areas where liquid radiopharmaceuticals were prepared for use or administered at the end of each day of use. However, the licensee does not need to perform the monitoring required by this Section in areas where patients or human research subjects are confined when they cannot be released under Section 335.2110 of this Part. The instrument shall be operable and calibrated in accordance with the requirements of 32 Ill. Adm. Code 340.510(b) and (c).

b) At least once each week, a licensee shall measure with a radiation measurement instrument capable of measuring dose rates over the range 10 μSv ~~mSv~~ (1 mrem) per hour to 10 mSv (1 rem) per hour all areas where radiopharmaceuticals or radioactive wastes are stored to ensure compliance with 32 Ill. Adm. Code 340.210 and 340.310. The instrument shall be operable and calibrated in accordance with the requirements of 32 Ill. Adm. Code 340.510(b) and (c).

c) At least once each week, a licensee shall measure for removable contamination in all areas where unsealed radioactive materials are prepared for use, administered or stored.

d) A licensee shall conduct the measurements required by subsections (b) and (c) ~~(d)~~ of this Section in a manner that permits detection of contamination on each wipe sample of 2000 dpm per 100 square centimeters of surface area.

e) A licensee shall retain a record of all monitoring and surveys required by this Section for 5 years. The record shall include the monitoring date, a sketch of each area monitored, the measured dose rate at several points in each area expressed in units, multiples or subunits of sieverts or rem per hour or the removable contamination in each area expressed in units, multiples or subunits of becquerels or curies per 100 square centimeters of surface area or in disintegrations (transformations) per minute per 100 square centimeters of surface area, the

manufacturer, model and serial number of the instrument used to perform the monitoring or analyze the samples and the identity of the individual who performed the monitoring.

AGENCY NOTE: A detection instrument means an uncompensated Geiger Mueller type instrument. A measurement instrument means an ion chamber or compensated Geiger Mueller instrument.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

SUBPART D: UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION AND EXCRETION STUDIES – WRITTEN DIRECTIVE NOT REQUIRED

**Section 335.3010 Use of Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is Not Required**

Except for quantities that require a written directive under Section 335.1110(a) of this Part, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution or excretion studies that is:

a) Obtained from a person specified in Section 335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements in Section 335.9040, or Sections 335.9050 and 335.9040(c)(1)(B)(vii), of this Part, or an individual under the supervision of either, as specified in Section 335.1050 of this Part; or

c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an application or protocol accepted by the FDA; or

d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an application or a protocol accepted by the FDA.

AGENCY NOTE: Participation in FDA research trials involving human subjects does not relieve the licensee from following all Agency regulations, whether or not they are included in the trial protocols. This includes participation in trials using "blind" research protocols.

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(Source: Amended at 32 Ill. Reg. _____, effective _____)

SUBPART E: UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED

**Section 335.4010 Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required**

Except for quantities that require a written directive under Section 335.1110(a) of this Part, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

a) Obtained from a person specified in Section 335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 335.9040, or Sections 335.9050 and 335.9040(c)(1)(B)(vii) of this Part, or an individual under the supervision of either, as specified in Section 335.1050 of this Part; or

c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an application or protocol accepted by the FDA; or

d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an application or a protocol accepted by the FDA.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS

**Section 335.9010 Radiation Safety Officer**

Except as provided in Section 335.9160 of this Part, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in Section 335.1040(b) of this Part to be an individual who:

a) Is certified by a specialty board whose certification process ~~includes all of the requirements in subsection (b) of this Section and whose certification~~ has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in subsections (e) and (f) of this section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements: ~~; or~~

1) The candidate must:

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

B) 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

C) Pass an examination administered by diplomate of the specialty board, which 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,

2) The candidate must:

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

B) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of

physicians who meet the requirements for authorized users in 335.9040 or 335.9050; and

(iii) Pass an examination, administered by diplomate of the specialty board, that assess 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:

1) 200 hours of classroom and laboratory ~~didactic~~ training in the following areas:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Radiation biology;

E) Radiation dosimetry; and

2) 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 Licensing State license or permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes similar types and uses of radioactive material involving the following:

A) Shipping, receiving and performing related radiation monitoring;

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

C) Securing and controlling radioactive material;

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

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

F) Using emergency procedures to control radioactive material;

G) Disposing of radioactive material; or ~~and~~

~~3) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (c)(1) and (2) of this Section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or~~

c) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State under Section 335.9150 (a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (e) and (f) of this section; or

d e) Is an authorized user, authorized medical physicist or authorized nuclear pharmacist identified on the licensee's license 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~~.~~

e) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsection (f) and (a)(1)(A) and (a)(1)(B) or (a)(2)(A) and (a)(2)(B) or meets subsections (c) or (d) and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee, and;

f) 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, authorized medical physicist, authorized nuclear

pharmacist or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

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

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9030 Training for Uptake, Dilution or Excretion Studies**

Except as provided in Section 335.9160 of this Part, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.3010 of this Part not requiring a written directive to be a physician who:

a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in subsection (c) of this Section and whose certification~~ has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in subsection (c)(3) of this Section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:~~; or~~

1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1) and (c)(2)(F) of this section; and

2) Pass an examination, administered by diplomate of the specialty board, which assess knowledge and competence in radiation safety, radionuclide handling and quality control; or

b) Is an authorized user under Section 335.9040 or 335.9050 with 335.9040(c)(1)(B)(vii) of this Part or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

c) Has completed a structured educational program consisting of: ~~60 hours of training and experience in basic radionuclide handling techniques applicable to~~

~~the medical use of unsealed radioactive material for uptake, dilution and excretion studies. The training and experience shall include, at a minimum:~~

1) 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies. The classroom and laboratory training shall include at a minimum:

~~1) Classroom and laboratory training in the following areas:~~

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience, under the supervision of an authorized user who meets the requirements in this Section, or Section 335.9040 or 335.9050 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements, involving :

A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation monitoring;

B) Performing quality control procedures on ~~Calibrating~~ instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical ~~reportable~~ event involving the use of unsealed radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages of radioactive drugs to patients or human research subjects; and

3) Has obtained written attestation ~~certification~~, signed by a preceptor authorized user who meets the requirements in this Section, or Section 335.9040 or 335.9050 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements, that the individual has satisfactorily completed the requirements in this subsection (a)(1) or (c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.3010 of this Part for those procedures not requiring a written directive.

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

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9040 Training for Imaging and Localization Studies**

Except as provided in Section 335.9160 of this Part, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.4010 of this Part not requiring a written directive to be a physician who:

a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in subsection (c) of this Section and whose certification~~ has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in subsection (c)(2). To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:~~; or~~

1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to

the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(A) and (c)(1)(B) of this section; and

2) Pass an examination, administered by diplomate of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

b) Is an authorized user under Section 335.9050 and meets the requirements of 335.9040(c)(1)(B)(vii) of this Part or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

c) Has completed a structured educational program consisting of: ~~700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:~~

1) 700 hours of training and experience, including 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:

A ~~1~~) Classroom and laboratory training in the following areas:

i ~~A~~) Radiation physics and instrumentation;

ii ~~B~~) Radiation protection;

iii ~~C~~) Mathematics pertaining to the use and measurement of radioactivity;

iv ~~D~~) Chemistry of radioactive material for medical use;

v ~~E~~) Radiation biology; and

B ~~2~~) Work experience, under the supervision of an authorized user who meets the requirements in this Section or Section 335.9050 and 335.9040(c)(1)(B)(vii) of this Section ~~Part~~ or equivalent U.S. Nuclear

Regulatory Commission, Agreement State or Licensing State requirements, involving:

i ~~A~~) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation monitoring;

ii ~~B~~) Performing quality control procedures on ~~Calibrating~~ instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;

iii ~~C~~) Calculating, measuring and safely preparing patient or human research subject dosages;

iv ~~D~~) Using administrative controls to prevent a medical ~~reportable~~ event involving the use of unsealed radioactive material;

v ~~E~~) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

vi ~~F~~) Administering dosages of radioactive drugs to patients or human research subjects;

vii ~~G~~) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring, and testing the eluate for radionuclidic purity and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2 ~~3~~) Has obtained written attestation ~~certification~~, signed by a preceptor authorized user who meets the requirements in this Section or Section 335.9050 and 335.9040 (c)(1)(B)(vii) of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements, that the individual has satisfactorily completed the requirements in this subsection (a)(1) or (c)(1) of this Section ~~(c)~~ and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.3010 and 335.4010 of this Part for those procedures not requiring a written directive.

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

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9050 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required**

Except as provided in Sections 335.9060, 335.9070 and 335.9160 of this Part, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.3010, 335.4010, or 335.5010 of this Part requiring a written directive to be a physician who:

a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in subsection (b) of this Section and whose certification~~ has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in paragraphs (b)(2)(F) and (b)(3) of this section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements: ~~; or~~

1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in subsection (b)(1) through (b)(2)(E) of this Section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

2) Pass an examination, administered by diplomate of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance and clinical use of unsealed radioactive materials; or

AGENCY NOTE: Specialty Boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory

Commission, an Agreement State or a Licensing State will be posted on the NRC's web page.

b) Has completed 700 hours of training and experience, including a minimum or 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include:

1) Classroom and laboratory training in the following areas:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience, under the supervision of an authorized user who meets the requirements in this Section or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements. A supervising authorized user, who meets the requirements in Section 335.9050(b)of this Part, shall have experience in administering dosages in the same dosage category or categories (i.e., Section 335.9050(b)(2)(F ~~G)(i), (ii), (iii), or (iv)~~ of this Part) as the individual requesting authorized user status. The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation monitoring;

B) Performing quality control procedures on ~~Calibrating~~ instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical ~~reportable~~ event involving the use of unsealed radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

~~F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs;~~

F ~~G~~) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

i) Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131, for which a written directive is required;

ii) Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131;

AGENCY NOTE: Experience with at least 3 cases in subsection (b)(2)(F ~~G~~)(ii) also satisfies the requirement in subsection (b)(2)(F ~~G~~)(i).

iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; and/or

iv) Parenteral administration of any other radionuclide for which a written directive is required; and

3) Has obtained written attestation ~~certification~~ that the individual has satisfactorily completed the requirements in subsections (a)(1) and (b)(2)(F) or (b)~~(1) and (2)~~ of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.5010 of this Part. The written attestation ~~certification~~ shall be signed by a preceptor authorized

user who meets the requirements in this Section, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements. The preceptor authorized user who meets the requirements in Section 335.9050(b) of this Part must have experience in administering dosages in the same dosage category or categories (i.e., Section 335.9050(b)(2)(F ~~G~~)~~(i), (ii), (iii), or (iv)~~ of this Part) as the individual requesting authorized user status.

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

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9060 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 GBq (33 mCi)**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized user for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi) to be a physician who:

a) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (c) (1) and (2) of this Section and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in subsection (c)(3) of this Section; or

b) Is an authorized user under Section 335.9050 of this Part for uses listed in Section 335.9050(b)(2)(F ~~G~~)(i) or (ii), or Section 335.9070 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

c) Has:

1) Successfully completed 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include :

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience under the supervision of an authorized user who meets the requirements ~~in subsection (a) or (b)~~ of this Section, Section 335.9050 or 335.9070 of this Part or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements. A supervising authorized user who meets the requirements of Section 335.9050(b) of this Part shall have experience in administering dosages as specified in Section 335.9050(b)(2)(F ~~G~~)(i) or (ii) of this Part. The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation monitoring;

B) Performing quality control procedures on ~~Calibrating~~ instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical ~~reportable~~ event involving the use of radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages to patients or human research subjects and shall include at least 3 cases involving the oral administration of

less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131; and

3) Obtained written attestation ~~certification~~ that the individual has satisfactorily completed the requirements in subsections (c)(1) and (2) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.5010 of this Part. The written attestation ~~certification~~ shall be signed by a preceptor authorized user who meets the requirements in this Section, or Section 335.9050, 335.9060 or 335.9070 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements. A preceptor authorized user who meets the requirements in Section 335.9050(b) of this Part must have experience in administering dosages as specified in Section 335.9050(b)(2)(F ~~G~~)(i) or (ii) of this Part.

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

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9070 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 GBq (33 mCi)**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi) to be a physician who:

a) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (c) (1) and (2) of this Section and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in subsection (c)(3) of this Section; or

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

b) Is an authorized user under Section 335.9050 of this Part for uses listed in Section 335.9050(b)(2)(F ~~G~~)(ii) of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

c) Has:

1) Successfully completed 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include :

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience under the supervision of an authorized user who meets the requirements in ~~subsection (a) or (b) of~~ this Section, Section 335.9050 of this Part or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements. A supervising authorized user who meets the requirements of Section 335.9050(b) of this Part shall have experience in administering dosages as specified in Section 335.9050(b)(2)(F ~~G~~)(ii) of this Part. The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation monitoring;

B) Performing quality control procedures on ~~Calibrating~~ instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical ~~reportable~~ event involving the use of radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages to patients or human research subjects and shall include at least 3 cases involving the oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131; and

3) Obtained written attestation ~~certification~~ that the individual has satisfactorily completed the requirements in subsections (c)(1) and (2) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.5010 of this Part. The written attestation ~~certification~~ shall be signed by a preceptor authorized user who meets the requirements in this Section or Section 335.9050 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements. A preceptor authorized user who meets the requirements in Section 335.9050(b) of this Part must have experience in administering dosages as specified in Section 335.9050(b)(2)(F ~~G~~)(ii) of this Part.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9080 Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive. ~~Training for Therapeutic Use of Soluble Phosphorus-32 (Repealed)~~**

Except as provided in Section 335.9160, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

a) Is an authorized user under Section 335.9050 for uses listed in subsections 335.9050(b)(2)(F)(iii) or 335.9050(b)(2)(F)(iv), or equivalent U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State requirements;

b) Is an authorized user under Sections 335.9100, 335.9140, or equivalent U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State requirements and who meets the requirements in paragraph (d) of this section; or

c) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State under Sections 335.9100 or 335.9140, and who meets the requirements in paragraph (d) of this section; or

(d) Has:

1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of byproduct material for medical use; and

E) Radiation biology; and

2) Work experience, under the supervision of an authorized user who meets the requirements in this section, Section 335.9050, or equivalent U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Section 335.9050 must have experience in administering dosages as specified in subsections 335.9050(b)(2)(F)(iii) or 335.9050(b)(2)(F)(iv). The work experience must involve:

A) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

C) Calculating, measuring, and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

E) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

F) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in this section and Section 335.9050, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 335.9050, must have experience in administering dosages as specified in subsections 335.9050(b)(2)(F)(iii) 335.9050(b)(2)(F)(iv).

(Source: Added at 32 Ill. Reg. _____, effective _____)

**Section 335.9100 Training for Use of Manual Brachytherapy Sources**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized user of a manual brachytherapy source in accordance with Section 335.7010 of this Part to be a physician who:

a) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in subsection (b) of this Section and whose certification~~ has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in Section

(b)(3) below. To be recognized, a specialty board shall require all candidates for certification to: ~~; or~~

1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

2) Pass an examination, administered by the diplomate of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of manual brachytherapy sources; or

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

b) Has:

1) Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

A) 200 hours of classroom and laboratory training in the following areas:

i) Radiation physics and instrumentation;

ii) Radiation protection;

iii) Mathematics pertaining to the use and measurement of radioactivity;

iv) Radiation biology; and

B) 500 hours of work experience under the supervision of an authorized user who meets the requirements in this Section or

equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements at a medical institution involving:

i) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation monitoring;

ii) Checking survey instruments for proper operation;

iii) Preparing, implanting and removing brachytherapy sources;

iv) Maintaining running inventories of material on hand;

v) Using administrative controls to prevent medical events involving ~~the misadministration of~~ radioactive material;

vi) Using emergency procedures to control radioactive material;

2) Completed 3 years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in this Section or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements as a part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (b)(1)(B) ~~(2)~~ of this Section; and

3) Obtained written attestation ~~certification~~, signed by a preceptor authorized user who meets the requirements in this Section or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements, that the individual has satisfactorily completed the requirements in subsections (a)(1) or (b)(1) and~~,~~ (b)(2) ~~and (3)~~ of this Section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under Section 335.7010 of this Part.

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9120 Training for Ophthalmic Use of Strontium-90**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiation therapy to be a physician who:

a) Is an authorized user under Section 335.9100 of this Part or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or

b) Has:

1) Completed 24 hours of classroom and laboratory training applicable to the use of strontium-90 for ophthalmic radiation therapy. The training shall include:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Radiation biology; and

2) Completed clinical training in ophthalmic radiation therapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of 5 patients. The supervised clinical training must include:

A) Examination of each patient to be treated;

B) Calculation of the dose to be administered;

C) Administration of the dose;

D) Follow-up and review of each patient's case history; and

3) Obtained written attestation ~~certification~~, signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9100 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements, that the individual has satisfactorily completed the requirements in subsections (a) and (b) ~~(b)(1) and (2)~~ of this Section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9140 Training for Use of Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized user of a sealed source for a use authorized under Section 335.8010 of this Part to be a physician who:

a) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (b)(3) and (b)(4) of this Section and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in paragraphs (b)(3) and (b)(4) of this section. To be recognized, a specialty board shall require all candidates for certification to: ~~; or~~

1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

2) Pass an examination, administered by diplomate of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

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

b) Has:

1) Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

A) 200 hours of classroom and laboratory training in the following areas:

i) Radiation physics and instrumentation;

ii) Radiation protection;

iii) Mathematics pertaining to the use and measurement of radioactivity;

iv) Radiation biology; and

B) 500 hours of work experience under the supervision of an authorized user who meets the requirements in this Part or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements at a medical institution that involves:

i) Reviewing full calibration measurements and periodic spot-checks;

ii) Preparing treatment plans and calculating treatment doses and times;

iii) Using administrative controls to prevent a medical ~~reportable~~ event involving the use of radioactive material;

iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

v) Checking and using survey instruments;

vi) Selecting the proper dose and how it is to be administered; and

2) Completed 3 years of supervised clinical experience in radiation therapy ~~oncology~~ under an authorized user who meets the requirements of this Section or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements as a part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (b)(1)(B) of this Section; and

3) Obtained written attestation ~~certification~~ that the individual has satisfactorily completed the requirements in subsection (a)(1) or (b)(1-2) and (b)(4)~~(2)~~ of this Section and has achieved a level of competency sufficient to function independently as an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation ~~certification~~ shall be signed by a preceptor authorized user who meets the requirements in this Section or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements for each type of therapeutic medical unit for which the individual is requesting authorized user status; and~~.~~

4) Has received training in device operation, safety procedures and clinical use for the types of use for which authorization is sought. This training requirement may be met by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9150 Training for Authorized Medical Physicist**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized medical physicist to be an individual who:

a) Is certified by a specialty board whose certification process ~~includes all of the training and experience requirements in subsection (b) of this Section and whose certification~~ has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and who meets the requirements in paragraphs (b)(2) and (c) of this section. To be recognized, a specialty board shall require all candidates for certification to: ~~; or~~

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

2) Have 2 years of full-time practical training and/or supervised experience in medical physics:

A) 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, an Agreement State or a Licensing State; or

B) In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytheraphy services under the direction of physicians who meet the requirements for authorized users in Sections 335.9100 or 335.9140 of this Part;

3) Pass an examination, administered by diplomate of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery.

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

b) Holds a master's degree or doctorate in physics, ~~biophysics, radiological physics,~~ medical physics or other physical science, engineering or applied mathematics from an accredited college or university ~~health physics~~; and

1) Has completed 1 year of full-time training in medical ~~therapeutic radiological~~ physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include: ~~at a medical institution that includes the tasks listed in Subparts H and I of this Part as applicable; and~~

A) Performing sealed source leak tests and inventories;

B) Performing decay corrections;

C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units and remote afterloading units as applicable;

D) Conducting radiation monitoring around external beam treatment units, stereotactic radiosurgery units and remote afterloading units as applicable; and

2) Has obtained written attestation ~~certification~~ that the individual has satisfactorily completed the requirements in subsection (a)(1)and (2) or (b)~~(1)~~ and (c) of this Section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation ~~certification~~ must be signed by a preceptor authorized medical physicist who meets the requirements of this Section or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9160 Training for Experienced Radiation Safety Officer, Authorized Medical Physicist or Authorized User**

a) An individual identified as a Radiation Safety Officer, or an authorized medical physicist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or a Licensing State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before October 24, 2007 ~~2004~~ need not comply with the training requirements of Sections 335.9010 and 335.9150 of this Part.

b) Physicians, dentists or podiatrists, identified as authorized users for the medical use of radioactive material on a license issued by the Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee on or before October 24, 2007 ~~2004~~ who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Sections 335.9030 through 335.9140 of this Part.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

**Section 335.9190 Resolution of Conflicting Requirements During Transition Period**

~~a)~~ 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 that licensee

exercises its privilege to amend its license, the portion amended must comply with the requirements of this Part.

~~b) Until October 24, 2007, the Agency will approve authorized users, Radiation Safety Officers and teletherapy physicists who have certifications from the applicable Boards specified in Appendix A of this Part. The Agency has the right to limit its authorizations to those uses specified in Appendix A of this Part.~~

(Source: Amended at 32 Ill. Reg. _____, effective _____)

Section 335.APPENDIX A List of Specialty Board Certifications Recognized by the Agency Until October 24, 2007 (Repealed)

~~Until October 24, 2007, the Agency will recognize board certification by the specialty boards for the uses of radioactive material as specified in this Appendix A. The Agency will also accept boards recognized by the U.S Nuclear Regulatory Commission and listed on its website.~~

~~Section 335.9010 Training for Radiation Safety Officer~~

~~American Board of Health Physics in Comprehensive Health Physics~~

~~American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics or Medical Nuclear Physics~~

~~American Board of Nuclear Medicine~~

~~American Board of Science in Nuclear Medicine~~

~~Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science~~

~~American Board of Medical Physics in Radiation Oncology Physics~~

~~Royal College of Physicians and Surgeons of Canada in Nuclear Medicine~~

~~Section 335.9030 Training for Uptake, Dilution or Excretion Studies~~

~~Nuclear medicine by the American Board of Nuclear Medicine~~

~~Radiology, with a specialization in radiation therapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"~~

~~Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons~~

~~Section 335.9120 Training for Ophthalmic Use of Strontium-90~~

~~Radiology or therapeutic radiology by the American Board of Radiology~~

~~Section 335.9130 Training for Use of Sealed Sources for Diagnosis~~

~~Radiology, diagnostic radiology, therapeutic radiology or radiation oncology by the American Board of Radiology~~

~~Nuclear medicine by the American Board of Nuclear Medicine~~

~~Diagnostic radiology or radiology by the American Osteopathic Board of Radiology~~

~~Nuclear medicine by the Royal College of Physicians and Surgeons of Canada~~

~~Section 335.9140 Training for Teletherapy~~

~~Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology~~

~~Radiation oncology by the American Osteopathic Board of Radiology~~

~~Radiology, with specialization in radiation therapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"~~

~~Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons~~

~~Section 335.9150 Training for Authorized Medical Physicist~~

~~Nuclear medicine by the American Board of Osteopathic Nuclear Medicine~~

~~Diagnostic radiology by the American Board of Radiology~~
~~Diagnostic radiology or radiology by the American Osteopathic Board of Radiology~~

~~Nuclear medicine by the Royal College of Physicians and Surgeons of Canada~~

~~Section 335.9040 Training for Imaging and Localization Studies~~

~~Nuclear medicine by the American Board of Nuclear Medicine~~

~~Nuclear medicine by the American Board of Osteopathic Nuclear Medicine~~

~~Diagnostic radiology by the American Board of Radiology~~

~~Diagnostic radiology or radiology by the American Osteopathic Board of Radiology~~

~~Nuclear medicine by the Royal College of Physicians and Surgeons of Canada~~

~~Section 335.9050 Training for Therapeutic Use of Unsealed Radioactive Material for Which a Written Directive is Required~~

~~The American Board of Nuclear Medicine~~

~~The American Board of Radiology in radiology, therapeutic radiology or radiation oncology~~

~~Section 335.9100 Training for Use of Sources for Brachytherapy~~

~~Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology~~

~~Radiation oncology by the American Osteopathic Board of Radiology~~

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~~American Board of Radiology in therapeutic radiological physics; roentgen ray and gamma ray physics; X-ray and radium physics; or radiological physics~~

~~American Board of Medical Physics in radiation oncology physics~~

(Source: Repealed at 32 Ill. Reg. _____, effective _____)

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1) Heading of the Part: Licensing of Radioactive Material

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

3)

| Section Number: | Proposed Action: |
|---|---|
| 330.20 | Amendment |
| 330.260 | Amendment |
| 330.280 | Amendment |
| 330.Appendix E | Repealed |

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

5) Effective Date of Amendments:

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

7) Does this rulemaking contain incorporations by reference? Yes

8) A copy of the adopted amendments, including any material incorporated by reference is on file at the Agency's headquarters located at 1035 Outer Park Drive, Springfield, Illinois and is available for public inspection.

9) Notice of Proposal Published in the Illinois Register: 32 Ill. Reg. 3455; March 14, 2008

10) Has JCAR issued a Statement of Objections to these Amendments? No

11) Differences between proposal and final version:
   a. In 330.260(c)(17) and (18) reformatted structure, resulting changed labels.
   b. In 330.260(c)(17) struck "Training for a nuclear pharmacy radiation safety officer.".
   c. In 330.260(c)(17)(B) added "met the requirements of subsections (D) and (E) of this Section."
   d. In 330.260(c)(17) struck existing subsections (C), (E) and (F) and added subsections (C) and (D).
   e. In 330.260 (c)(18)(B) changed "200 hours of classroom and laboratory training" to "200 hours of didactic training"

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12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreement letter issued by JCAR? Section 31 of the Radiation Protection Act exempts from the IAPA's general rulemaking requirements IEMA rulemakings that are identical in substance to NRC rules and necessary to implement, secure or maintain federal authorization for an IEMA program.

13) Will these amendments replace an emergency rule currently in effect? No

14) Are there any amendments pending on this Part? No

15) Summary and Purpose of amendments: These regulations provide for training of authorized user physicians for medical use of radionuclides. These changes are considered Compatibility A, B and C or a Health and Safety standard by the U.S. Nuclear Regulatory Commission (NRC) and must be adopted essentially verbatim by the Agency in order to maintain it's "Agreement State" status. This rulemaking will ensure compatibility with the NRC's 10 CFR 20, 30, 23, 35, 40 and 70 regulations currently in place for medical use of radioactive materials. The changes are mandated in 70 FR 16336 (RATS ID #2005-2) and 71 FR 15005 (RATS ID #2006-1). Agreement States such as Illinois are required to have these regulations in place by April 29, 2008 and March 27, 2009.

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 NRC has reviewed the proposed amendments and the text has been revised to incorporate its suggested changes.

16) Information and questions regarding these adopted amendments shall be directed to:

Louise Michels
Staff Attorney
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, Illinois 62704
(217) 785-9876

ILLINOIS EMERGENCY MANAGEMENT AGENCY

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The full text of the Adopted Amendment begins on the next page:

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED 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

AUTHORITY: Implementing and authorized by the Radiation Protection Act of 1990 [420 ILCS 40].

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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. _____, effective _____ _____.

SUBPART A: GENERAL PROVISIONS

**Section 330.20 Definitions**

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

Meets the requirements in Section 330.260(c)(18), (c)(19) and (c)(21) of this Part; 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) of this Part.

"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.

"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.

(Source: Amended at 32 Ill. Reg. _____, effective _____)

SUBPART C: SPECIFIC AND GENERAL LICENSES

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

**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 of this Part;

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 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;

3) The applicant submits information on the radionuclide, chemical and physical form, packaging, including maximum activity per package, and shielding provided by the packaging of the radioactive material that is appropriate for safe handling and storage of radiopharmaceuticals by specific licensees;

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 accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to subsection (a) of this Section for radioactive material specified in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by this subsection (c)(4) are in addition to the labeling required by the U.S. Food and Drug Administration (FDA) and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA;

5) 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;

6) 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 must 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 must 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;

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, other Federal and 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 perform radiometric tests for molybdenum breakthrough for the first elute of a molybdenum-99/technetium-99m generator following transfer in accordance with the requirements of 32 Ill. Adm. Code 335;

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) For licensees authorized to dispense radiopharmaceuticals (such as nuclear pharmacies), the licensee shall ensure 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 must 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 of this subsection (c)(15) is responsible for the acts and omissions of the supervised individual;

16) A licensee shall apply for and must receive a license amendment identifying an authorized nuclear pharmacist as defined in 32 Ill. Adm. Code 330.20, and the individual meets the requirements in 330.260(c)(18) and 330.260(c)(21) or for an experienced nuclear pharmacist, 330.260(c)(20), ~~as an authorized nuclear pharmacist~~ before it allows this individual to work as an authorized nuclear pharmacist;

17) ~~Training for a nuclear pharmacy radiation safety officer.~~ The licensee shall require an individual fulfilling the responsibilities of Radiation Safety Officer 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, an Agreement State or a Licensing State and who meets the requirements in subsections (D) and (E) of this section. 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 or 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 diplomats of the specialty board, which 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 (D) and (E) of this Section 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; radiation dosimetry; and

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 Licensing State license or permit issued by the 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) Has obtained written attestation certification, signed by a preceptor authorized nuclear pharmacist Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections A(i-ii) (c)(17)(B)(i) and (ii) of this Section and has achieved a level of radiation safety knowledge sufficient to function independently as an authorized nuclear pharmacist Radiation Safety Officer.~~

CD) Is an authorized nuclear pharmacist identified on the licensee's license, meets the requirements of subsections (D) and (E) of this Section 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

DE) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist Radiation Safety Officer, that the individual has satisfactorily completed the requirements in Subsection (E) and subsections (c)(17)(A)(i) and (ii) or (B) or (C) of this Section and has achieved a level of radiation safety knowledge sufficient to function independently as an authorized nuclear pharmacist Radiation Safety Officer; and ~~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 or authorized nuclear pharmacist, as appropriate, who is authorized for the types of use for which the licensee is seeking approval.~~

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

~~F) Is an individual identified as a Radiation Safety Officer, or an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or a Licensing State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State broad scope license or master material license permit or by a master material license permittee of broad scope on or before October 24, 2007;~~

18) Before a licensee permits anyone to work as an authorized nuclear pharmacist under his or her ~~their~~ license, except for subsection (c)(19) of this Section, the licensee shall require the authorized nuclear pharmacist to be a State of Illinois licensed pharmacist who:

A) ~~Has current board certification as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties on or before October 24, 2007, or~~ Is ~~is~~ certified as a nuclear pharmacist by a specialty board whose certification process ~~includes all of the requirements in subsection (c)(18)(B)(A)(i) of this Section and whose certification~~ has been recognized by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and who meets the requirements in subsections (B)(iii) of this subsection. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:~~; or~~

i) Has graduated from a pharmacy program accredited by the American Council of Pharmaceutical Education ACPE or have passed 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 the diplomats of the specialty board, that assessed knowledge and competency in the procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

B ~~i~~) 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; radiation biology; and

~~3 ii) Mathematics pertaining to the use and measurement of radioactivity;~~

~~4 iii) Chemistry of byproduct material for medical use; and~~

~~5 iv) Radiation biology; and~~

ii ~~B~~) 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 byproduct material; use of procedures to prevent or

minimize radioactive contamination and use of proper decontamination procedures; and ~~the following~~:

~~1~~ i) ~~Shipping, receiving, and performing related radiation surveys;~~

~~2~~ ii) ~~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;~~

~~3 C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;~~

~~4 D) Use of administrative controls to avoid medical events in the administration of byproduct material;~~

~~5 E) Use of procedures to prevent or minimize radioactive contamination and use of proper decontamination procedures; and~~

iii ~~F~~) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (A)(i-iii) or (B) ~~(c)(18)(A)(i)~~ of this Section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist;

19) An individual identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State license or permit issued by an Agency, U.S. Nuclear Regulatory Commission, Agreement State broad scope licensee or master materials license permit or by a master materials license permittee of broad scope ~~on or before October 24, 2007 need not comply with the training requirements of subsection (c)(18)(A)(i) of this Section~~;

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) ~~A)(i)~~ of this Section 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) of this Section must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed;

22) Resolution of Conflicting Requirements During Transition Period

A) 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.

~~B) Until October 24, 2007, the Agency will approve authorized nuclear pharmacists who have certifications from the applicable Boards specified in Appendix E of this Part. The Agency has the right to limit authorization to those uses specified in Appendix E of this Part.~~

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, an Agreement State or a Licensing State will be posted on the NRC's Web page.

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 32 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 a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material and estimated concentration of the radioactive material in the product or material at the time of transfer; and

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

2) Each person licensed under 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 following:

A) 5 years after filing the preceding report; or

B) Filing an application for renewal of the license under Section 330.330; or

C) Notifying the Agency under Section 330.320(b) of the licensee's decision to permanently discontinue 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 subsection (a) during the reporting period, the report shall so indicate.

5) The licensee shall maintain the record of a transfer for a period of 1 year after the event has been included in a report to the Agency.

b) Licensing the Distribution of Radioactive Material in Exempt Quantities

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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.

1) An application for a specific license to distribute NARM to persons exempted, pursuant to Section 330.40(b) of this Part, will be approved if:

   A) The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

   B) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product or device intended for commercial distribution; and

   C) The applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

2) The license issued under subsection (b)(1) of this Section is subject to the following conditions:

   A) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

   B) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Section 330.40(b). The outer package shall be

such that the dose rate at the external surface of the package does not exceed 5 microSv (500 microrem) per hour.

C) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label that:

i) Identifies the radionuclide and activity; and

ii) Bears the words "Radioactive Material".

D) In addition to the labeling information required by subsection (b)(2)(C) of this Section, the label affixed to the immediate container, or an accompanying brochure, shall:

i) State that the contents are exempt from Licensing State requirements;

ii) Bear the words "Radioactive Material – Not for Human Use – Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals or into Products Manufactured for Commercial Distribution is Prohibited – Exempt Quantities Should Not Be Combined"; and

iii) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

3) Each person licensed under this subsection (b) is required to maintain records and file reports as follows:

A) Records of transfer of material identifying, by name and address, each person to whom radioactive material is transferred for use under Section 330.40(b) of this Part or the equivalent regulations of an Agreement State, or a Licensing State and stating the kinds and quantities of radioactive material transferred. The licensee shall maintain the record of a transfer for a period of 1 year after the event is included in a summary report to the Agency.

B) The licensee shall file a summary report stating the total activity of each radioisotope transferred under the specific license with the Agency.

C) The licensee shall file the summary report within 30 days following:

i) 5 years after filing the preceding report; or

ii) Filing an application for renewal of the license under Section 330.330 of this Part; or

iii) Notifying the Agency under Section 330.320(b) of this Part of the licensee's decision to permanently discontinue activities authorized under the license issued under subsection (b) of this Section.

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

c) Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Section 330.40(c)(3) of this Part will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, published January 1, 1993, exclusive of subsequent amendments or editions. The maximum activity of radium-226 in each device shall not exceed 3.7 kBq (100 nCi).

d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under Section 330.220(b) of this Part

AGENCY NOTE: Section 330.280(n) of this Part contains requirements for radioactive material transfer reports and records.

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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(b) of this Part or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

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

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

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

ii) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in 32 Ill. Adm. Code 340.210(a); and

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

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

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

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

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

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

ii) The requirement, or lack of requirement, for testing for leakage or contamination, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by radionuclide, activity and activity assay date; and

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

Devices Containing Radioactive Material Other Than Naturally Occurring Radioactive Material

The receipt, possession, use and transfer of this device, Model ___ , Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL
Name of Manufacturer or Distributor

AGENCY NOTE: The model, serial number and name of the manufacturer or distributor may be omitted from this

label provided the information is elsewhere specified in labeling affixed to the device.

Devices Containing Naturally-Occurring Radioactive Material

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 a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

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) (2005) 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.

2) Except as provided in this subsection, the interval between tests for proper operation of the on-off mechanism and indicator, if any, shall not exceed 6 months. The interval between tests for contamination of the device or for leakage of radioactive material from the device or for both shall not exceed 3 months for devices containing sources designed to emit alpha

particles and 6 months for all other devices. In the event the applicant desires that the device be required to be tested at intervals longer than the above, the applicant shall include in the application sufficient information to demonstrate that such longer intervals are justified. The information shall include a description of the performance characteristics of the device or similar devices and of design features that have a significant bearing on the probability or consequences of contamination of the device or leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material or contamination of the device, the Agency will consider information that includes, but is not limited to:

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material; and

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

3) In the event the applicant desires that the general licensee under Section 330.220(b) of this Part, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of, or contamination by, radioactive material, service the device, test the on-off mechanism and indicator or

remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, is unlikely to cause that individual to receive an annual dose in excess of 10 percent of the limits specified in 32 Ill. Adm. Code 340.210(a).

4) A person licensed under subsection (d) of this Section to distribute devices to generally licensed persons shall provide the information in subsection (d)(4) of this Section to each person to whom a device is to be transferred for possession and use under the general license in Section 330.220(b) of this Part. 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(b) of this Part;

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

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

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

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

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

5) A person licensed under this subsection (d) to distribute devices to generally licensed persons shall provide the information in this subsection (d)(5) to each person to whom a device is to be transferred for possession and use under a general license equivalent to Section 330.220(b) of this Part in the regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing 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 10 CFR 31.5, 31.2, 30.51, 20.2201 and 20.2202 (2005) or the equivalent regulations of an Agreement State or Licensing State. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the applicable Agreement State or Licensing State regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State or Licensing 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 the U.S. Nuclear Regulatory Commission and most Agreement States and Licensing States to take escalated enforcement action for improper disposal; and

E) The name or title, address and phone number of the contact at the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State regulatory agency from whom additional information may be obtained.

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

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

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

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

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

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

B) The applicant satisfies the requirements of 10 CFR 32.53-32.55 and 32.101, published January 1, 1993, exclusive of subsequent amendments or editions, or their equivalent.

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(c) of this Part or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The report shall identify each general licensee by name and address, state the kinds and numbers of luminous devices transferred and specify the activity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter.

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(e) of this Part. 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(e) of this Part will be approved if:

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

2) The applicant satisfies the requirements of 10 CFR 32.57 and 70.39 published January 1, 1993 and certifies that the applicant will satisfy, and subsequently satisfies, the requirements of 10 CFR 32.58, 32.59 and 32.102, published January 1, 1993, 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(f) of this Part, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, will be approved if:

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

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) One of the following statements, as appropriate, or a statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

A) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

B) 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 a Licensing State.

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 such radioactive material. In the case of the mock iodine-125 reference or calibration source, the manufacturer shall state in the directions that this item shall be disposed of in compliance with 32 Ill. Adm. Code 340.1010(a).

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(g) of this Part, will be approved if:

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

2) The criteria of 10 CFR 32.61, 32.62 and 32.103 published January 1, 1993, exclusive of subsequent amendments or editions, are met.

i) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses. An application for a specific license to manufacture and distribute radiopharmeceuticals containing radioactive material for use by persons licensed pursuant to Section 330.260(a) 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 of this Part;

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 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;

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 which is appropriate for safe handling and storage of radiopharmaceuticals by specific licensees; and

4) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, activity and activity assay date and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a) for radioactive material specified in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by this subsection (i) are in addition to the labeling required by the FDA and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

j) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material

AGENCY NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have such reagent kits approved by the Agency for use by persons licensed pursuant to Section 330.260(a) of this Part 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) of this Part 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 of this Part;

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) of this Part and 32 Ill. Adm. Code 335.4010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing 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) of this Part for use as a calibration or reference source or for the uses listed in 32 Ill. Adm. Code 335.6010, 335.7010 and 335.8010 will be approved if:

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

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

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

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

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

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

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

F) Procedures and standards for calibrating sources and devices;

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

H) Instructions for handling and storing sources or devices from the radiation safety standpoint. These instructions shall be included on

a durable label attached to each source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;

3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, activity and activity assay date, radiation symbol and/or "Caution Radioactive Material", serial number, model, manufacturer name or logo, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a) of this Part and 32 Ill. Adm. Code 335.7010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, provided that the labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;

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

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

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material;

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

K) Proposed use of source.

l) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Section 330.210(d) of this Part or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

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

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

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

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

D) Furnish:

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

the general license contained in Section 330.210(d) of this Part; or

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

E) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in Section 330.210(d) of this Part. Such 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 such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Section 330.210(d) of this Part during the reporting period, the report shall so indicate;

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

quarter in which such product or device is transferred to the generally licensed person. The licensee shall report:

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

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

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

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

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

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

1) An application for license to manufacture, import or initially distribute sealed sources or devices containing sealed sources for initial transfer to

persons having a specific license to receive such sealed sources or devices will be approved subject to the following conditions:

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

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 of this Part.

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

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

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

i) Proposed uses for the sealed source;

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

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

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

v) Radiation profile of a prototype sealed source;

vi) Procedures for and results of prototype testing;

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

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

ix) Leak testing procedures; and

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

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

i) Proposed uses for the device;

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

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

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

v) Radiation profile of a prototype device;

vi) Procedures for and results of prototype testing;

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

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

ix) Leak testing procedures;

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

xi) Information about installation, service and maintenance procedures;

xii) Handling, operating and safety instructions; and

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

D) When evaluating a sealed source or device, the Agency will apply the radiation safety criteria described in 10 CFR 32.210(d), published January 1, 1993, exclusive of subsequent amendments or editions.

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

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

ii) The provisions of the evaluation sheet prepared by the Agency and submitted to the U.S. Department of Health and Human Services for filing in the "Radioactive Material Reference Manual", or to the U.S. Nuclear Regulatory Commission for filing in the "Registry of Radioactive Sealed Sources and Devices".

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 of this Part 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) One of the following statements, as appropriate, or a statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure that accompanies the package:

A) This radiopharmaceutical may be received, possessed and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

B) 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 a Licensing State.

o) Material Transfer Reports and Records
Each person licensed under subsection (d) of this Section to distribute devices to generally licensed persons shall comply with the requirements of subsection (n) of this Section.

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(b) of this Part or the equivalent regulations of the

U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State;

B) To the Agency and to the responsible regulatory agency all receipts of devices from persons generally licensed under Section 330.220(b) of this Part or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing 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) of this Section that is furnishing the report and shall include the person's specific license number.

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

(Source: Amended at 32 Ill. Reg. _____, effective _____)

Section 330.APPENDIX E List of Specialty Board Certifications Recognized by the Agency Until October 24, 2007 (Repealed)

~~Until October 24, 2007, the Agency will recognize Board certification by the specialty boards for the uses of radioactive material as specified in this Appendix. The Agency will also accept boards recognized by the U.S. Nuclear Regulatory Commission and listed on its website.~~

~~Training for Authorized Nuclear Pharmacist~~

~~Board of Pharmaceutical Specialties in Nuclear Pharmacy or Sciences~~

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

(Source: Repealed at 32 Ill. Reg. _____, effective _____)

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: |
|---|---|
| 330.40 | Amendment |
| 330.260 | Amendment |
| 330.280 | Amendment |

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

5) A Complete Description of the Subjects and Issues Involved: Part 330.260(c) clarifies language for the manufacturing of radiopharmaceuticals and specifies who can prepare these products including the credentialing process. Language was also added to include the type of sources to be manufactured under 330.280(k).

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 100.335: No studies or reports were used in drafting this amendment to 32 Ill. Adm. Code 330

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

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

9) Does this rulemaking contain incorporations by reference? No

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

11) Statement of Statewide Policy Objective: The requirements imposed by the proposed rulemaking are 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 proposed 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:

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENTS

Kevin McClain
Chief Legal Counsel
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, Illinois 62704
(217) 524-0770 (voice)
(217) 782-6133 (TDD)

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities or not for profit corporations affected:

B) Reporting, bookkeeping or other procedures required for compliance: None

C) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized:

The full text of the Proposed Amendments begins 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

Section


SUBPART B: TYPES OF LICENSES

Section


SUBPART C: SPECIFIC AND GENERAL LICENSES

Section

SUBPART D: TRANSPORTATION



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;

**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 ~~of this Part~~;

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; or

D) Operating as a nuclear pharmacy within a Federal medical institution;

3 ~~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 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;

~~3) The applicant submits information on the radionuclide, chemical and physical form, packaging, including maximum activity per package, and shielding provided by the packaging of the radioactive material that is appropriate for safe handling and storage of radiopharmaceuticals by specific licensees;~~

~~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 accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to subsection (a) of this Section for radioactive material specified in 32 Ill. Adm. Code 335.3010, 335.4010 or 335.5010, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by this subsection (c)(4) are in addition to the labeling required by the U.S. Food and Drug Administration (FDA) and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA;~~

4 ~~5~~) 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 ~~6~~) 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 must 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 must 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) of this Section:

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 subsection (c)(6)(B) and (D) of this Section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 32 Ill. Adm. Code 330.260(c)(15).

(B) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 330.20;

(ii) This individual meets the requirements specified in 330.260(c)(18)(B) and 330.260(c)(21), and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (c)(6)(D) of this Section.

(C) The actions authorized in subsections (c)(6)(A) and (B) of this Section are permitted in spite of more restrictive language in license conditions.

(D) 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 NRC.

(E) Shall provide to the Agency:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State as specified in Section 330.260(c)(18)(A) with the written attestation signed by a preceptor as required by 330.260(18)(B)(iii); or

(ii) A NRC or Agreement State license, or

(iii) NRC master materials licensee permit, or

(iv) The permit issued by a licensee or NRC master materials permittee of broad scope or the 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 NRC; and

(vi) A copy of the State pharmacy licensure or registration prior to allowing, under subsections (6)(B)(i) and (6)(B)(iii) of this Section, the individual to work as an authorized nuclear pharmacist.

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, other Federal and 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 perform radiometric tests for molybdenum breakthrough for the first elute of a molybdenum-99/technetium-99m generator following transfer in accordance with the requirements of 32 Ill. Adm. Code 335;

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) For licensees authorized to dispense radiopharmaceuticals (such as nuclear pharmacies), the licensee shall ensure 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 must 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 of this subsection (c)(15) is responsible for the acts and omissions of the supervised individual;

16) A licensee shall apply for and must receive a license amendment identifying an authorized nuclear pharmacist as defined in 32 Ill. Adm. Code 330.20, and the invididual meets the requirements in 330.260(c)(18) and 330.260(c)(21) or for an experienced nuclear pharmacist, 330.260(c)(20) before it allows this individual to work as an authorized nuclear pharmacist;

17) The licensee shall require an individual fulfilling the responsibilities of Radiation Safety Officer 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, an Agreement State or a Licensing State and who meets the requirements in subsections (D) and (E) of this Section ~~section~~. 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 or 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 diplomats of the specialty board, which 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 (D) and (E) of this Section 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; radiation dosimetry; and

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 Licensing State license or permit issued by the 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 (D) and (E) of this Section 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) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsection ~~Subsection~~ (E) and subsections (c)(17)(A)(i) and (ii) or (B) or (C) of this Section and has achieved a level of radiation safety knowledge sufficient to function independently as an authorized nuclear pharmacist Radiation Safety Officer; and

E) 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 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 anyone to work as an authorized nuclear pharmacist under his or her license, except for subsection (c)(19) of this Section, 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, Agreement State or Licensing State and who meets the requirements in subsections (B)(iii) of this subsection. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:

i) Has graduated from a pharmacy program accredited by the American Council of Pharmaceutical Education ACPE or have passed 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 the diplomats of the specialty board, that assessed knowledge and competency in the 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 ot the use and measurement of radioactivity; chemistry of radioactive material for medical use; 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 byproduct 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 subsection (A)(i-iii) or (B) of this Section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist;

19) An individual identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State license or permit issued by an Agency, U.S. Nuclear Regulatory Commission, 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) of this Section 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) of this Section must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed;

22) Resolution of Conflicting Requirements During Transition Period

A) 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~~.

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, an Agreement State or a Licensing State will be posted on the NRC's Web page.

(Source: Amended at 32 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**

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) ~~of this Part~~ for use as a calibration 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 ~~of this Part~~;

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

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

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

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

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

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

F) Procedures and standards for calibrating sources and devices;

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

H) Instructions for handling and storing sources or devices from the radiation safety standpoint. These instructions shall be included on a durable label attached to each source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label;

3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, activity and activity assay date, radiation symbol and/or "Caution Radioactive Material", serial number, model, manufacturer name or logo, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to Section 330.260(a) or (b) ~~of this Part~~ and 32 Ill. Adm. Code 335.2040, 335.2140, 335.6010, 335.7010 and 335.8010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, provided that the labeling for sources that do not require long-term storage may be on a leaflet or brochure that accompanies the source;

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

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

A) Primary containment or source capsule;

B) Protection of primary containment;

C) Method of sealing containment;

D) Containment construction materials;

E) Form of contained radioactive material;

F) Maximum temperature withstood during prototype tests;

G) Maximum pressure withstood during prototype tests;

H) Maximum activity of contained radioactive material;

I) Radiotoxicity of contained radioactive material;

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

K) Proposed use of source.