

ILLINOIS REGISTER

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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) 

<u>Section Number:</u>	<u>Proposed Action:</u>
335.30	Amendment
335.2030	Amendment
335.2110	Amendment
335.3010	Amendment
335.4010	Amendment
335.4020	Amendment
335.5010	Amendment
335.5020	Amendment
335.8040	Amendment
335.8160	Amendment
335.9010	Amendment
335.9030	Amendment
335.9040	Amendment
335.9050	Amendment
335.9060	Amendment
335.9070	Amendment
335.9080	Amendment
335.9100	Amendment
335.9120	Amendment
335.9140	Amendment
335.9150	Amendment
335.9160	Amendment
- 4) Statutory Authority: Implementing and authorized by Section 10 of the Radiation Protection Act of 1990 [420 ILCS 40/10].
- 5) Effective Date of Amendments:
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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: 34 Ill. Reg. 14634; October 8, 2010
- 10) Has JCAR issued a Statement of Objections to these Amendments? No
- 11) Differences between proposal and final version: Several grammatical and stylistic changes were made in accordance with JCAR's recommendation. In Section 335.2030, restored (b)(2)(c) and changed "330.240 (a)(12)" to "330.260(c)(23)".
- 12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreement letter issued by JCAR? Yes
- 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 proposed amendments will ensure compatibility with the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR 35 regulations currently in place for medical use of radioactive materials. Agreement States such as Illinois are required to have these changes in place by October 29, 2010. NRC has assigned this rulemaking a compatibility category of B. This means that the Illinois rule must have language essentially identical to NRC's because of transboundary considerations. This rulemaking clarifies physician qualifications for human use of radioactive materials and makes reference to NRC guidance for assessment of radiation dose. It also revises certain quality control tests and clarifies requirements for medical use of accelerator-produced radioactive material.

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 has indicated that these amendments are needed to ensure compatibility with 10 CFR 35. Because this rulemaking is not subject to the Illinois Administrative Procedure Act, and in accordance

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

with Section 31, this rulemaking will become effective following the first notice period immediately upon filing for adoption with the Secretary of State or at a date required or authorized by the relevant federal laws, regulations, or orders as stated in the notice of the rulemaking, and shall be published in the Illinois Register.

- 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 Amendments begin on the next page:

ILLINOIS REGISTER

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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

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 335.2020 Possession, Calibration and Check of Survey Instruments (Repealed)
- 335.2030 Assay of Radiopharmaceutical Dosages
- 335.2040 Authorization for Calibration, Transmission, Attenuation Correction and Reference Sources
- 335.2050 Requirements for Possession of Sealed Sources (Repealed)
- 335.2060 Labeling and Use of Vials and Syringes
- 335.2070 Vial Shields and Vial Shield Labels (Repealed)
- 335.2080 Monitoring for Contamination and Ambient Radiation Dose Rate
- 335.2090 Safety Instructions for Patients Not Hospitalized and Containing Therapeutic Doses of Radiopharmaceuticals or Permanent Implants (Repealed)
- 335.2100 Admission of Patients Being Treated with Radiopharmaceuticals or Permanent Implants (Repealed)
- 335.2110 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
- 335.2120 Mobile Medical Service Requirements
- 335.2130 Storage of Volatiles and Gases (Repealed)
- 335.2140 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (Emerging Technologies)

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

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
- 335.4020 Permissible Concentrations of Molybdenum-99, Strontium-82 and Strontium-85 Concentration
- 335.4030 Control of Aerosols and Gases (Repealed)

SUBPART F: UNSEALED RADIOACTIVE MATERIAL -WRITTEN DIRECTIVE REQUIRED

ILLINOIS REGISTER

---

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Section  
335.5010 Use of Unsealed Radioactive Material for Which a Written Directive is Required  
335.5020 Safety Instruction  
335.5030 Safety Precautions

SUBPART G: SEALED SOURCES FOR DIAGNOSIS

Section  
335.6010 Use of Sealed Sources for Diagnosis

SUBPART H: MANUAL BRACHYTHERAPY

Section  
335.7010 Use of Sealed Sources for Manual Brachytherapy  
335.7020 Safety Instruction  
335.7030 Safety Precautions  
335.7040 Accountability and Security of Brachytherapy Sources  
335.7050 Discharge of Patients Treated With Temporary Implants (Repealed)  
335.7060 Surveys After Source Implant and Removal  
335.7070 Calibration Measurements of Brachytherapy Sources  
335.7080 Decay of Brachytherapy Sources  
335.7090 Therapy-related Computer Systems for Manual Brachytherapy

SUBPART I: REMOTE AFTERLOADER UNITS,  
INTRAVASCULAR BRACHYTHERAPY UNITS,  
TELETHERAPY UNITS AND  
GAMMA STEREOTACTIC RADIOSURGERY UNITS

Section  
335.8010 Use of a Sealed Source in Remote Afterloader Units, Intravascular Brachytherapy  
Units, Teletherapy Units or Gamma Stereotactic Radiosurgery Units  
335.8020 Installation, Maintenance, Adjustment and Repair  
335.8030 Amendments to Teletherapy Licenses (Repealed)  
335.8040 Safety Procedures and Instructions for Remote Afterloader Units, Intravascular  
Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Radiosurgery  
Units  
335.8050 Safety Precautions for Remote Afterloader Units, Teletherapy Units and Gamma  
Stereotactic Radiosurgery Units

ILLINOIS REGISTER

---

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 335.8060 Radiation Monitoring Device for Teletherapy Units and Gamma Stereotactic Radiosurgery Units
- 335.8070 Viewing System for Teletherapy (Repealed)
- 335.8080 Dosimetry Equipment
- 335.8090 Full Calibration Measurements for Teletherapy
- 335.8100 Periodic Spot-Checks for Teletherapy
- 335.8110 Radiation Monitoring
- 335.8120 Safety Checks for Teletherapy Facilities (Repealed)
- 335.8130 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program (Repealed)
- 335.8140 Reports of Teletherapy Monitoring, Checks, Tests and Measurements (Repealed)
- 335.8150 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
- 335.8160 Full Calibration Measurements on Remote Afterloader Units
- 335.8170 Periodic Spot-Checks for Remote Afterloader Units
- 335.8180 Monitoring of Patients and Human Research Subjects Treated with a Remote Afterloader Unit or Intravascular Brachytherapy Unit
- 335.8190 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units
- 335.8200 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units
- 335.8210 Additional Technical Requirements for Mobile Remote Afterloader Units
- 335.8220 Additional Technical Requirements for Intravascular Brachytherapy Units
- 335.8230 Therapy-related Computer Systems for Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Units

SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS

Section

- 335.9010 Radiation Safety Officer
- 335.9020 Training for Experienced Radiation Safety Officer (Repealed)
- 335.9030 Training for Uptake, Dilution or Excretion Studies
- 335.9040 Training for Imaging and Localization Studies
- 335.9050 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required
- 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)
- 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)
- | 335.9080 Training for the Parenteral Administration of Unsealed Radioactive Byproduct Material Requiring a Written Directive

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 335.9090 Training for Therapeutic Use of Colloidal Chromic Phosphorus-32 Labeled Phosphate Compound or Gold-198 (Repealed)
- 335.9100 Training for Use of Manual Brachytherapy Sources
- 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 (Repealed)

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. 9247, effective June 13, 2008; amended at 3534 Ill. Reg. \_\_\_\_, effective \_\_\_\_\_.

SUBPART A: GENERAL INFORMATION

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Section 335.30 License Required

- a) A person shall manufacture, produce, acquire, receive, possess, prepare, ~~may only use or transfer~~ radioactive material ~~or a radioactive sealed source~~ for medical use ~~only that is:~~
  - 1-) ~~manufactured, produced, acquired, received, possessed, prepared or transferred~~ in accordance with a specific license issued by ~~the Agency in~~

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

~~accordance with 32 Ill. Adm. Code 330.260(e), 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 by~~ subsection (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.

~~e) 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.~~

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**SUBPART C: GENERAL TECHNICAL REQUIREMENTS**

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**Section 335.2030 Assay of Radiopharmaceutical Dosages**

- a) A licensee shall determine and record the activity of each dosage before medical use.
- b) For a unit dosage, this determination shall be made by:
  - 1) Direct measurement of radioactivity by the licensee; or

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 2) For radiopharmaceuticals with a photon emitting radionuclide not requiring a written directive, a decay correction, based on the activity or activity concentration determined by:
  - A) A manufacturer or preparer authorized under Section 335.30 ~~of this Part~~ or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements; or
  - B) An Agency, U.S. Nuclear Regulatory Commission, ~~or~~ Agreement State ~~or Licensing State~~ licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; ~~or~~
  - C) A PET radioactive drug producer licensed under 32 Ill. Adm. Code 330.260(c)(23) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.
- c) For other than unit dosages, this determination shall be made by:
  - 1) Direct measurement of radioactivity by the licensee;
  - 2) ~~A combination~~ ~~Combination~~ of measurement of radioactivity and mathematical calculations; or
  - 3) ~~A combination~~ ~~Combination~~ of volumetric measurements and mathematical calculations; based on the measurement made by a manufacturer or preparer licensed under Section 335.30 ~~of this Part~~ or equivalent U.S. Nuclear Regulatory Commission, ~~or~~ Agreement State ~~or~~ ~~Licensing State~~ requirements.
- d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.
- e) A licensee shall maintain a record of dosage determinations required by subsection (a) of this Section for 5 years.
- f) The record shall contain:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 1) The radiopharmaceutical;
- 2) The patient's or human research subject's name, or identification number if one has been assigned;
- 3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30  $\mu$ Ci);
- 4) The date and time of the dosage determination;
- 5) If more than 15 minutes have elapsed between the time of dosage determination and dosage administration, the date and time of dosage administration; and
- 6) The name of the individual who determined the dosage.

AGENCY NOTE: If a unit dose has been manipulated in any way, it is no longer considered a unit dose and shall be measured by the licensee before administration.

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 335.2110 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material**

- a) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem) following assessment of the patient's medical, living and working conditions.

AGENCY NOTE: NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," published October 2002, exclusive of subsequent amendments or editions, describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

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ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- b) If the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem), the licensee shall provide the released individual and, as determined appropriate by the authorized physician user, the individual's spouse, parent, guardian or other primary caregiver, with verbal and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If the total effective dose equivalent to a minor, pregnant individual, or nursing infant or child could exceed 1 mSv (0.1 rem), assuming there were no interruptions of breast-feeding, the instructions shall also include:
- 1) Guidance on the interruption or discontinuation of breast-feeding;
  - 2) Guidance on minimizing close ~~and~~/or extended contact; and
  - 3) Information on the potential consequences, if any, of failure to follow the guidance.
- c) Release of the patient pursuant to this Section shall be approved by an authorized physician user who is approved for the applicable use of radioactive material ~~(i.e., under Subpart F or Subpart H of this Part)~~. The authorized user physician shall state in writing that he or she is ~~professionally~~ satisfied that patient compliance with necessary instructions is likely and ~~that~~ the patient is suitable for release.
- d) A licensee shall retain a record for 5 years after the release of the individual for the following:
- 1) The basis for authorizing the release of an individual in accordance with subsections (a) and (b) of this Section to include the assessment and evaluation criteria for the patient's medical, living and working conditions, activities of radioactive material used (i.e., retained or administered activity), occupancy factors, biological or effective half-life of radioactive material, shielding by tissue, and means of estimating doses to any other individual and the physicians.
  - 2) The instructions for each patient required by subsection (b) of this Section.
  - 3) The physician's certification for patient release required by subsection (c) of this Section.

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

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

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**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 ~~subsection~~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, ~~or Agreement State~~ ~~or Licensing State~~ requirements; or
- b) ~~Excluding production of PET radionuclides, prepared~~Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements in Section 335.9040, or a combination of Sections 335.9050 and ~~subsection~~ 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, ~~or 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.

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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

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

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Except for quantities that require a written directive under ~~subsection~~ ~~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; ~~or Agreement State~~ ~~or Licensing State~~ requirements; or
- b) ~~Excluding production of PET radionuclides, prepared~~ Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 335.9040; ~~or a combination of Sections 335.9050 and subsection 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; ~~or 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 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 335.4020 Permissible Concentrations of Molybdenum-99, Strontium-82 and Strontium-85 Concentration**

- a) A licensee ~~shall~~ may not administer to humans a radiopharmaceutical that contains more than: ~~0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 μCi of molybdenum-99 per mCi of technetium-99m)~~.

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 1) 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 $\mu$ Ci of molybdenum-99 per mCi of technetium-99m);
- 2) 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02  $\mu$ Ci of strontium-82 per mCi of rubidium-82); or
- 3) 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2  $\mu$ Ci of strontium-85 per mCi of rubidium-82).

b) ~~A licensee that uses molybdenum-99/technetium-99m generators for preparing technetium-99m radiopharmaceuticals shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to~~ To demonstrate compliance with subsection (a) of this Section, a licensee shall measure:-

- 1) The concentration of molybdenum-99 in the first eluate after receipt of a molybdenum-99/technetium-99m generator; and
- 2) The concentration of strontium-82 and strontium-85 for the first patient use of the day on each day that a strontium-82/rubidium-82 generator is used.

c) A licensee shall maintain a record of the ~~molybdenum-99~~ concentration tests required by subsection (b) of this Section for 5 years. The record ~~shall~~ ~~must~~ include for each measurement, ~~for each measured elution of technetium-99m, the ratio of the measures expressed as kBq of molybdenum per MBq of technetium-99m (or  $\mu$ Ci of molybdenum per mCi of technetium),~~ the time and date of the measurement, ~~and~~ the name of the individual who made the measurement ~~and, for the corresponding measurement in subsection (b) of this Section:-~~

- 1) The ratio of the measure expressed as kBq of molybdenum per MBq of technetium-99m (or  $\mu$ Ci of molybdenum per mCi of technetium); or
- 2) The ratios of the measures expressed as kBq of strontium-82 per MBq of rubidium-82 and kBq of strontium-85 per MBq of rubidium-82 (or  $\mu$ Ci of strontium per mCi of rubidium).

d) A licensee shall report immediately to the Agency each occurrence of ~~molybdenum-99~~ a concentration exceeding the limits specified in subsection (a) of this Section.

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**SUBPART F: UNSEALED RADIOACTIVE MATERIAL-WRITTEN DIRECTIVE  
REQUIRED**

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

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

- a) Obtained from a person specified in Section 335.30 ~~of this Part~~, or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements;
- b) ~~Excluding production of PET radionuclides, prepared Prepared~~ by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 335.9040 or a combination of Section 335.9050 and subsection 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, or Agreement State ~~or Licensing State~~ licensee for use in research in accordance with a protocol accepted by FDA; or
- d) Prepared by the licensee for use in research in accordance with an application or a protocol accepted by FDA.

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 335.5020 Safety Instruction**

In addition to the requirements of 32 Ill. Adm. Code 400.120:

- a) A licensee shall provide ~~in~~ radiation safety instruction, prior to beginning work and at least annually, to personnel caring for patients or human research subjects who have been administered radioactive materials requiring a written directive. To satisfy this requirement, the instructions shall ~~must~~ be commensurate with the duties of the personnel and shall include:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 1) Patient or human research subject control;
  - 2) Visitor control, including:
    - A) Routine visitation to hospitalized individuals in accordance with 32 Ill. Adm. Code 340.310(a)(1); and
    - B) Visitation authorized in accordance with 32 Ill. Adm. Code 340.310(c);
  - 3) Contamination control;
  - 4) Waste control; and
  - 5) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.
- b) A licensee shall maintain a record of safety instructions required by this Section for 5 years. The record ~~shall~~**must** include a list of the topics covered, the date of the instruction, the names of the attendees and the names of the individuals who provided the instruction.

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**SUBPART I: REMOTE AFTERLOADER UNITS, INTRAVASCULAR BRACHYTHERAPY UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS**

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**Section 335.8040 Safety Procedures and Instructions for Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units**

- a) A licensee using sealed sources in remote afterloader units, intravascular brachytherapy units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses shall:

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 1) Secure the unit, the console, the console keys and the treatment room when not in use or unattended, if applicable;
  - 2) Permit only individuals approved by the authorized user, Radiation Safety Officer or authorized medical physicist to be present in the treatment room during treatment or emergencies with the sources;
  - 3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and
  - 4) Develop, implement and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sources in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures ~~shall~~**must** include:
    - A) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
    - B) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
    - C) The names and telephone numbers of the authorized users, the authorized medical physicist and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- b) A copy of the procedures required by subsection (a)(4) of this Section and the manufacturer's instruction manual ~~shall~~**must** be physically located at the unit console.
- c) A licensee shall post instructions at the unit console to inform the operator of:
- 1) The ~~location of the~~ procedures **located there as** required by subsection ~~(b)(a)(4)~~ of this Section; and
  - 2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:
  - 1) The procedures identified in subsection (a)(4) of this Section; and
  - 2) The operating procedures for the unit.
- e) A licensee shall ensure that operators, authorized medical physicists and authorized users participate in drills of the emergency procedures, initially and at least annually.
- f) A licensee shall retain a record of ~~the individuals receiving~~ instruction required by subsection (d) of this Section. ~~The record shall be retained for five years and include a list of the topics covered, the date of the instruction, the names of the attendees and the names of the individuals who provided instruction.~~
- ~~g) A licensee shall maintain a record of safety instructions required by this Section for 5 years. The record must include a list of the topics covered, the date of the instruction, the names of the attendees and the names of the individuals who provided the instruction.~~
- g) A licensee shall retain a copy of the procedures required by subsections (a)(4) and (d)(2) of this Section until the licensee no longer possesses the remote afterloader, intravascular brachytherapy unit, teletherapy unit or gamma stereotactic radiosurgery unit.
- h) A licensee shall maintain a copy of the record documenting results of the drills of emergency procedures required by subsection (e) of this Section for 5 years.

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 335.8160 Full Calibration Measurements on Remote Afterloader Units**

- a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
  - 1) Before the first medical use of the unit;

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 2) Before medical use under the following conditions:
  - A) Following replacement of the source or following reinstallation of the unit in a new location outside the facility;
  - B) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;
- 3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
- 4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

b) To satisfy the requirement of subsection (a) of this Section, full calibration measurements ~~shall~~**must** include, as applicable, determination of:

- 1) The output within  $\pm 5$  percent;
- 2) Source positioning accuracy to within  $\pm 1$  millimeter;
- 3) Source retraction with backup battery upon power failure;
- 4) Length of the source transfer tubes;
- 5) Timer accuracy and linearity over the typical range of use;
- 6) Length of the applicators; and
- 7) Function of the source transfer tubes, applicators and transfer tube-applicator interfaces.

c) A licensee shall use the dosimetry system described in ~~subsection~~**Section** 335.8080(a) ~~of this Part~~ to measure the output.

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- d) A licensee shall make full calibration measurements required by subsection (a) of this Section in accordance with published protocols accepted by nationally recognized bodies.
- e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection (b) of this Section, a licensee shall perform an autoradiograph of the sources to verify inventory and sources arrangement at intervals not exceeding 1 quarter.
- f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections (a) through (e) of this Section.
- g) A licensee shall mathematically correct the outputs determined in subsection (b)(1) of this Section for physical decay at intervals consistent with 1 percent physical decay.
- h) Full calibration measurements required by subsection (a) of this Section and physical decay corrections required by subsection (g) of this Section ~~shall~~ must be performed by the authorized medical physicist.
- i) A licensee shall maintain a record of the remote afterloader unit full calibrations required by this Section for 5 years.
- j) The records ~~shall~~ must include for each full calibration required by subsection (a) of this Section:
  - 1) The date of the calibration;
  - 2) The manufacturer's name, model and serial number of the remote afterloader units, together with the sources and the instruments used to calibrate ~~it~~ the units;
  - 3) The results and an assessment of the full calibrations;
  - 4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

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ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 5) The signature of the authorized medical physicist who performed the full calibration.

(Source: Amended at ~~3534~~ Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS**

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**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 under the requirement in subsection~~ ~~Section~~ 335.1040(b) ~~of this Part~~ to be an individual who:

- a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, ~~or an Agreement State or a Licensing State~~ and who ~~has obtained the attestation and training described meets the requirements~~ in subsections (e) and (f) of this ~~S~~section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:
- 1) The candidate ~~shall~~~~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 that evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry; or
- 2) The candidate ~~shall~~~~must~~:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- A) Hold a master's or ~~doctorate~~~~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 Sections 335.9040, ~~or~~ 335.9050 or 335.9160; and
  - iii) Pass an examination; administered by diplomate of the specialty board; that ~~evaluates~~~~assess~~ knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or
- b) Has ~~obtained the attestation and training described in subsections (e) and (f) of this Section and has~~ completed a structured educational program consisting of:
  - 1) 200 hours of 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) 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.

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ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Nuclear Regulatory Commission; or Agreement State ~~or Licensing State~~ license or permit issued by ~~at~~ 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
- c) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency; ~~under subsection 335.9150(a) or the~~ 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 ~~radioactive byproduct~~ material for which ~~the licensee is seeking the~~ approval of the individual as Radiation Safety Officer ~~is sought and who has obtained the attestation and training described meets the requirements~~ in subsections ~~(e) and (f)~~ ~~(e) and (d)~~ of this ~~S~~ection; or
- d) Is an authorized user; ~~or~~ 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)~~

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

~~and (a)(1)(A) and (a)(1)(B) or (a)(2)(A) and (a)(2)(B) or meets subsections (e) 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

- 1) Has satisfactorily completed the requirements described in:
  - A) Subsection (f) of this Section and subsections (a)(1)(A) and (B) of this Section; or
  - B) Subsection (f) of this Section and subsections (a)(2)(A) and (B) of this Section; or
  - C) Subsections (b) and (f) of this Section; or
- 2) Meets the criteria of subsection (c) or (d) of this Section and has received the training required by subsection (f) of this Section.

f) Has ~~received~~ training in radiation safety, regulatory issues and emergency procedures for the types of use for which ~~a licensee seeks approval is sought~~. This training requirement may be satisfied by completing training that is supervised by a ~~R~~adiation ~~S~~safety ~~O~~fficer, authorized medical physicist, authorized nuclear pharmacist or authorized user, as appropriate, who is authorized for the types~~(s)~~ of use for which ~~the licensee is seeking approval is sought~~.

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

(Source: Amended at 3534 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 has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, ~~or an~~

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ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Agreement State ~~or a Licensing State~~ and who has obtained the attestation required by ~~meets the requirements in~~ subsection (d)(~~e~~)(3) of this Section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:

- 1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed ~~radioactive byproduct~~ material for uptake, dilution and excretion studies as described in subsections (c)(1) and (2) of this Section ~~that includes the topics listed in subsections (e)(1) and (e)(2); and~~
  - 2) Pass an examination, administered by diplomate of the specialty board, that ~~evaluates~~ ~~assesses~~ knowledge and competence in radiation safety, radionuclide handling and quality control; or
- b) Is an authorized user ~~who meets the requirements of~~ ~~under~~ Section 335.9040; or ~~Sections~~ 335.9050 ~~and 335.9040(e)(1)(B)(vii);~~ or equivalent U.S. Nuclear Regulatory Commission; ~~or Agreement State~~ ~~or Licensing State~~ requirements; or
- c) Has ~~obtained the attestation described in subsection (d) of this Section and has~~ completed a structured educational program consisting of:
- 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:
    - 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

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 2) Work experience, under the supervision of an authorized user who meets the requirements in this Section, ~~or Section 335.9040, or 335.9050 or 335.9160 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 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 event involving the use of unsealed radioactive material;
  - E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; ~~and~~
  - F) Administering dosages of radioactive drugs to patients or human research subjects. ~~; and~~
- d3) Has obtained written attestation, ~~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) of this Section or in subsection (a)(1)~~ and has achieved a level of competency sufficient to function independently as an authorized user for the ~~medical~~ uses authorized ~~by under~~ Section 335.3010 ~~of this Part for those procedures not requiring a written directive~~. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section or Section 335.9040, 335.9050 or 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

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ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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

(Source: Amended at 3534 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 has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, ~~or an Agreement State or a Licensing State~~ and who ~~has obtained the attestation described~~ ~~meets the requirements~~ in subsection (d) of this Section ~~(e)(2)~~. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:
  - 1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed ~~radioactive byproduct~~ material for imaging and localization studies ~~as described in that includes the topics listed in~~ subsections ~~(c)(1)(A) and (e)(1)(B)~~ of this Section; and
  - 2) Pass an examination; administered by diplomate of the specialty board, that ~~evaluates~~ ~~assesses~~ knowledge and competence in radiation safety, radionuclide handling and quality control; or
- b) Is an authorized user ~~under Section 335.9050 and who~~ meets the requirements of Section 335.9050 and subsection (c)(2)(G) of this Section ~~335.9040(e)(1)(B)(vii)~~ or equivalent U.S. Nuclear Regulatory Commission; or Agreement State ~~or Licensing State~~ requirements; or
- c) Has ~~obtained the attestation described in subsection (d) of this Section and has completed a structured educational program consisting of:~~
  - +) 700 hours of training and experience, including 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include, at a minimum:

- 1A) Classroom and laboratory training in the following areas:
  - Ai) Radiation physics and instrumentation;
  - Bi) Radiation protection;
  - Cii) Mathematics pertaining to the use and measurement of radioactivity;
  - Di) Chemistry of radioactive material for medical use;
  - Ei) Radiation biology; and
- 2B) Work experience, under the supervision of an authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050 together with subsection (c)(2)(G) and 335.9040 (e)(1)(B)(vii) of this Section, or equivalent U.S. Nuclear Regulatory Commission, or Agreement State or Licensing State requirements, involving:
  - Ai) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation monitoring;
  - Bi) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;
  - Cii) Calculating, measuring and safely preparing patient or human research subject dosages;
  - Di) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
  - Ei) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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

~~Gvii)~~ 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~~

~~d2)~~ Has obtained written attestation, ~~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 described in subsection (a)(1), (b) or (c)(~~+~~) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Sections 335.3010 and 335.4010 ~~of this Part for those procedures not requiring a written directive.~~ The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050 together with subsection (c)(2)(G) of this Section or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

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

(Source: Amended at 3534 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, 335.9080 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:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, ~~or an Agreement State or a Licensing State~~ and who **has the work experience required by meets the requirements in** subsections (b)(2)(F) of this Section and **has obtained the attestation described in subsection (c)(b)(3)** of this Section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:

- 1A) 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 subsections (b)(1) through (b)(2)(E) of this Section. Eligible training programs ~~shall~~**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;
- 2B) Pass an examination, ~~administered by diplomate of the specialty board,~~ that ~~evaluates~~**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, ~~or an Agreement State or a Licensing State~~ will be posted on the NRC's ~~website~~**Web page**.

- b) Has **obtained the attestation described in subsection (c) of this Section and has completed 700 hours of training and experience, including a minimum of 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;

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ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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, ~~Section 335.9160~~ or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements. A supervising authorized user, who meets the requirements in ~~subsection Section 335.9050~~(b) of this ~~SectionPart~~, shall have experience in administering dosages in the same dosage category or categories (i.e., ~~subsectionSection 335.9050~~(b)(2)(F) of this ~~SectionPart~~) 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 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 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 involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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 described in subsection (b)(2)(F)(ii) of this Section also satisfies the requirement in subsection (b)(2)(F)(i) of this Section.

- 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

- c3) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (b) of this Section or subsections (a)(1) and of this Section together with subsection (b)(2)(F) or (b) 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 shall be signed by a preceptor authorized user who meets the requirements in this Section; or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission; or Agreement State or Licensing State requirements. The preceptor authorized user who meets the requirements in subsection Section 335.9050(b) of this Section Part shall must have experience in administering dosages in the same dosage category or categories (i.e., subsection (b)(2)(F) of this Section) as the individual requesting authorized user status.

AGENCY NOTE: Specially 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 REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 3534 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, ~~or an Agreement State or a Licensing State~~ and who ~~has obtained the attestation described~~ ~~meets the requirements~~ in subsection (d) ~~(e)(3)~~ of this Section; or
- b) Is an authorized user ~~who meets the requirements of Section 335.9070 or under Section 335.9050 of this Part for the uses identified listed in subsection~~ Section 335.9050(b)(2)(F)(i) or (ii), ~~or Section 335.9070 of this Part~~, or equivalent U.S. Nuclear Regulatory Commission, ~~or Agreement State or Licensing State~~ requirements; or
- c) Has ~~obtained the attestation described in subsection (d) of this Section and 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

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 2) Work experience under the supervision of an authorized user who meets the requirements of this Section, Section 335.9050, ~~or Section 335.9070, or 335.9160~~ or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements. A supervising authorized user who meets the requirements of ~~subsection~~ **Section 335.9050(b) of this Part** shall have experience in administering the dosages ~~identified as specified in subsection~~ **Section 335.9050(b)(2)(F)(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 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 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~~
- d3) ~~Has obtained~~ **Obtained** written attestation that the individual has satisfactorily completed the requirements in subsections (a) or (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 shall be signed by a preceptor authorized user who meets the requirements in this Section, ~~or Section 335.9050, 335.9060 or 335.9070, 335.9160 of this Part,~~ or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements. ~~The~~ **A** preceptor

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

authorized user who meets the requirements in Section 335.9050(b) ~~of this Part shall~~ must have experience in administering the dosages identified as specified in ~~subsection~~ Section 335.9050(b)(2)(F)(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; or an Agreement State ~~or a Licensing State~~ will be posted on the NRC's ~~website~~ Web page.

(Source: Amended at 3534 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; or an Agreement State ~~or a Licensing State~~ and who has obtained the attestation described ~~meets the requirements~~ in subsection (d) ~~(e)(3)~~ of this Section; or

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

- b) Is an authorized user ~~who meets the requirements of~~ ~~under~~ Section 335.9050 ~~of this Part~~ for the uses identified ~~listed~~ in ~~subsection~~ Section 335.9050(b)(2)(F)(ii) ~~of this Part~~, or equivalent U.S. Nuclear Regulatory Commission; or Agreement State ~~or Licensing State~~ requirements; or
- c) Has ~~obtained the attestation described in subsection (d) of this Section and has:~~

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ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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 this Section, Section 335.9050, ~~335.9160 of this Part,~~ or equivalent U.S. Nuclear Regulatory Commission, ~~or 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 the dosages ~~identified as specified in subsection~~ ~~Section~~ 335.9050(b)(2)(F)(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 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 event involving the use of radioactive material;
  - E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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~~

~~d3)~~ Has ~~obtained~~ ~~Obtained~~ written attestation that the individual has satisfactorily completed the requirements in subsections (a) or (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 shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, ~~335.9160 of this Part~~, or equivalent U.S. Nuclear Regulatory Commission, ~~or Agreement State or Licensing State~~ requirements. ~~The~~ A preceptor authorized user who meets the requirements in Section 335.9050(b) ~~shall of this Part must~~ have experience in administering the dosages ~~identified as specified in subsection~~ ~~Section~~ 335.9050(b)(2)(F)(ii) ~~of this Part~~.

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 335.9080 Training for the Parenteral Administration of Unsealed Radioactive ~~Byproduct~~ Material Requiring a Written Directive**

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 ~~who meets the requirements of under~~ Section 335.9050 for a use ~~listed identified~~ in subsections 335.9050(b)(2)(F)(iii) or (iv) ~~335.9050(b)(2)(F)(iv);~~ or equivalent U.S. Nuclear Regulatory Commission, ~~or Agreement State, or Licensing State~~ requirements; or
- b) Is an authorized user under Section 335.9100 or 335.9140; ~~or 335.9160 or~~ equivalent U.S. Nuclear Regulatory Commission, ~~or Agreement State, or Licensing State~~ requirements and who meets the requirements in subsection (d) of this ~~S~~section and has obtained the attestation described in subsection (e) of this Section; or
- c) Is certified by a medical specialty board whose certification process has been recognized by the Agency; ~~under Section 335.9100 or 335.9140 or by~~ the U.S.

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

Nuclear Regulatory Commission; or an Agreement State ~~or a Licensing State under Section 335.9100 or 335.9140~~. The individual shall ~~and who~~ meet the requirements in subsection (d) of this Section and have obtained the attestation described in subsection (e) of this Section; or

- d) Has ~~obtained the attestation described in subsection (e) of this Section and has:~~
- 1) Successfully completed 80 hours of classroom and laboratory training applicable to parenteral administrations of radioactive material; for which a written directive is required. ~~The training shall apply to~~ 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 shall ~~must~~ include:
    - A) Radiation physics and instrumentation;
    - B) Radiation protection;
    - C) Mathematics pertaining to the use and measurement of radioactivity;
    - D) Chemistry of ~~radioactive 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, 335.9160 or equivalent U.S. Nuclear Regulatory Commission; or Agreement State; ~~or Licensing State~~ requirements; in the parenteral administration; of radioactive material for which a written directive is required. ~~The experience shall include administration 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 shall~~ ~~must~~ have experience in administering dosages as ~~identified~~ ~~specified~~ in Section 335.9050(b)(2)(F)(iii) or ~~335.9050(b)(2)(F)~~(iv). The work experience shall ~~must~~ involve:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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 ~~radioactive~~~~byproduct~~ material;
  - E) Using procedures to contain spilled ~~radioactive~~~~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; ~~of radioactive material for which a written directive is required.;~~ ~~This experience shall include administration 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.;
- ~~e3)~~ ~~Has obtained-Obtained~~ written attestation that the individual has satisfactorily completed the requirements in subsection (b), ~~or~~ (c) or (d) of this ~~S~~ection; and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed ~~radioactive~~~~byproduct~~ material requiring a written directive. The ~~written~~-attestation ~~shall~~~~must~~ be signed by a preceptor authorized user who meets the requirements in this ~~S~~ection, ~~and~~ Section 335.9050, 335.9160 or equivalent U.S. Nuclear Regulatory Commission; or Agreement State; ~~or Licensing State~~ requirements. ~~The~~A preceptor authorized user who meets the requirements in Section 335.9050 ~~shall~~~~must~~ have experience in administering dosages ~~identified as specified in subsections~~Section 335.9050(b)(2)(F)(iii) or 335.9050(b)(2)(F)(iv).

AGENCY NOTE: Specialty boards whose certification processes have been

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

(Source: Amended at 3534 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 under the provisions and requirements of Subpart H 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 has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, ~~or an Agreement State~~ or a Licensing State and who has obtained the attestation described meets the requirements in subsection (c) of this Section ~~(b)(3) below~~. To be recognized, a specialty board shall require all candidates for certification to:
- 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 that evaluate 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, ~~or an Agreement State~~ or a Licensing State will be posted on the NRC's ~~website~~ Web page.

- b) Has obtained the attestation described in subsection (c) of this Section and has:
- 1) Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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 **at a medical institution** under the supervision of an authorized user who meets the requirements in this Section or **Section 335.9160** or equivalent U.S. Nuclear Regulatory Commission; ~~or Agreement State~~ ~~or Licensing State~~ requirements. **The work experience shall include: 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 radioactive material;
  - vi) Using emergency procedures to control radioactive material; and
- 2) Completed 3 years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in this Section or **Section 335.9160** or equivalent U.S. Nuclear Regulatory Commission; ~~or Agreement State~~ ~~or Licensing State~~ requirements. **The experience shall be**

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

obtained 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~~

- c3) ~~Has obtained~~ written attestation, ~~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 subsection (a)(1), or ~~(b) subsections (b)(1) and (2),~~ 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 Subpart H. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. ~~Section 335.7010 of this Part.~~

(Source: Amended at 3534 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 ~~who meets the requirements of~~ Section 335.9100 ~~of this Part~~ or equivalent U.S. Nuclear Regulatory Commission, ~~or Agreement State or Licensing State~~ requirements; or
- b) Has ~~obtained the attestation described in subsection (c) of this Section and 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:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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 ~~shall~~**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**
- ~~c3)~~ **c3)** ~~Has obtained~~**Obtained** written attestation, ~~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) of this Section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use. **The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9100, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.**

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

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

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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 the provisions and requirements of Subpart I 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, ~~or an Agreement State or a Licensing State~~ and who ~~has obtained the attestation described in~~ ~~meets the requirements in~~ subsections (c) ~~(b)(3) and (b)(4)~~ of this Section ~~and the training required by subsection (d) of this Section~~. To be recognized, a specialty board shall require all candidates for certification to:

- 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,~~ that ~~evaluates 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, ~~or an Agreement State or a Licensing State~~ will be posted on the NRC's ~~website~~ ~~Web page~~.

- b) Has ~~obtained the attestation described in subsection (c) of this Section, the training required by subsection (d) of this Section and 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:

ILLINOIS REGISTER

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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

- 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 **at a medical institution** under the supervision of an authorized user who meets the requirements in this ~~Section Part~~ or **Section 335.9160** or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements. **The work experience shall include 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 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 under an authorized user who meets the requirements of this Section or **Section 335.9160** or equivalent U.S. Nuclear Regulatory Commission, or Agreement State or ~~Licensing State~~ requirements. **The experience shall be obtained as a** part of a formal training program approved by the Residency

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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~~

- c3) ~~Has obtained~~ ~~Obtained~~ written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) ~~;~~ ~~or (b)(1-2)~~ and (d) ~~or (b) and (d)(b)(4)~~; of this Section and has achieved a level of competency sufficient to function independently as an authorized user for ~~the each~~ type of therapeutic medical unit for which the individual is requesting authorized user status. The ~~written~~ attestation shall be signed by a preceptor authorized user who meets the requirements in this Section ~~or Section 335.9160~~ or equivalent U.S. Nuclear Regulatory Commission ~~;~~ ~~or Agreement State~~ ~~or Licensing State~~ requirements for each type of therapeutic medical unit for which the individual is requesting authorized user status. ~~;~~ ~~and~~
- d4) Has received training in device operation, safety procedures and clinical use for the types of ~~therapeutic medical unit~~ ~~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 ~~by the equipment supplier~~ 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.

AGENCY NOTE: The term “type of therapeutic medical unit” refers to a type of use identified in this Section. It applies to this Section only. Training for therapeutic medical units is not manufacturer-specific. Training for one brand of therapeutic medical unit is acceptable for another brand of the same type of unit.

(Source: Amended at 3534 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:

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

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

- 1) Hold a master's degree or doctorate 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, ~~or 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 brachytherapy services under the direction of physicians who meet the requirements for authorized users in Section 335.9100, ~~or 335.9140~~ ~~or 335.9160 of this Part~~;
- 3) Pass an examination, ~~administered by diplomate of the specialty board,~~ that ~~evaluates~~ ~~assesses~~ knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery; ~~or-~~

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

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

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

4) Has completed 1 year of full-time training in medical 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~~type(s) of use for which the individual is seeking authorization. This training and work experience ~~shall~~must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and ~~shall~~must include:

1A) Performing sealed source leak tests and inventories;

2B) Performing decay corrections;

3C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units and remote afterloading units as applicable;

4D) Conducting radiation monitoring around external beam treatment units, stereotactic radiosurgery units and remote afterloading units, as applicable; and

c2) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (a)(1), ~~and (a)(2) or (b)~~ and (e)(d) or subsections (b) and (d) of this Section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of ~~use~~therapeutic medical unit for which the individual is requesting authorized medical physicist status. The ~~written~~attestation ~~shall~~must be signed by a preceptor authorized medical physicist who meets the requirements of this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission, or Agreement State ~~or Licensing State~~ requirements for an authorized medical physicist for each type of ~~use~~therapeutic medical unit for which the individual is requesting authorized medical physicist status.

de) Has training ~~in~~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 an ~~equipment supplier~~the vendor or by training supervised by an authorized medical

ILLINOIS REGISTER

ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF ADOPTED AMENDMENTS

physicist authorized for the type~~(s)~~ of use for which the individual is seeking authorization.

(Source: Amended at 3534 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~~;~~ or Agreement State ~~or a Licensing State~~ license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission~~;~~ or 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 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~~;~~ or 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~~;~~ or 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 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~~.
- c) **Individuals who are not subject to the training requirements in this Section may serve as preceptors for and supervisors of applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.**

(Source: Amended at 3534 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)