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ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENT

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SUBCHAPTER b: RADIATION PROTECTION

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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 35 Ill. Reg. 884, effective December 30, 2010; amended at 37 Ill. Reg. 12406, effective July 19, 2013; recodified at 45 Ill. Reg. 10286; amended at 46 Ill. Reg. 966, effective December 21, 2021; amended at 47 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL INFORMATION

Section 335.20 Definitions

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

"Associate Radiation Safety Officer" means an individual who, for this Part only, meets the requirements in Sections 335.9010 and 335.9180 and is currently identified as an

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Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on a specific medical use license issued by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State or on medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

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

"Authorized medical physicist" means an individual who meets the requirements in Sections 335.9150(a) and 335.9180; or is identified as an authorized medical physicist or teletherapy physicist on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope medical use licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

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

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

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

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

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interpreting the final results, which may be images, graphs or numbers.

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

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

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

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

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

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

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

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

"Medical institution" means: an organization in which more than one medical discipline is practiced.

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

~~A medical clinic, private practice or mobile nuclear medicine service that holds a~~

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~~specific license issued by the Agency and is authorized under Section 335.2140, 335.5010 (for therapy procedures only), 335.7010 or 335.8010 to use radioactive material.~~

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

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

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

"Ophthalmic physicist" means an individual who meets the requirements in Sections 335.7100(b) and 335.9180; and is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

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

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

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

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

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

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

in a written directive; or

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

"Prescribed dose" means:

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

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

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

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

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

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

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

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"Radiation Safety Officer" means an individual who:

meets the requirements in Sections 335.9010 and 335.9180; or

is identified as a Radiation Safety Officer on:

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

a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

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

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

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

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

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

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

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

"Visiting authorized user" means a temporary (i.e., less than 60 days each year) authorized user who is not identified on the license of the licensee being visited and who

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has been approved by the Radiation Safety Committee in accordance with Section 335.1060(b).

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

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 335.40 License Amendments

For specific licenses issued pursuant to 32 Ill. Adm. Code 330.260(a) or 330.260(b), a licensee's management shall apply for and shall receive a license amendment:

- a) Before using radioactive material for any use not permitted by the license;
- b) Before permitting anyone to work as an authorized user, authorized medical physicist, or ophthalmic physicist under the license, except:
 - 1) For a visiting authorized user, as described in Section 335.1060;
 - 2) For an authorized user, an individual who meets:
 - A) The requirements in 335.9180; and
 - B) The applicable board certification requirements in subsections 335.9030(a), 335.9040(a), 335.9050(a), 335.9060(a), 335.9070(a), 335.9100(a), 335.9130(a), and 335.9140(a);
 - 3) For an authorized medical physicist, an individual who meets the requirements in subsection 335.9150(a) and Section 335.9180;
 - 4) An individual who is identified as an authorized user, an authorized medical physicist, or an ophthalmic physicist on an Agency, [NRC U.S. Nuclear Regulatory Commission](#), or Agreement State license or other equivalent permit recognized by the Agency that authorizes the use of byproduct material in medical use, on a permit issued by the Agency, [NRC, the U.S. Nuclear Regulatory Commission](#) or an Agreement State specific license of broad scope that is authorized to permit the use of

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byproduct material in medical use, or on a permit issued by ~~the~~ [NRC U.S. Nuclear Regulatory Commission](#) master material licensee that is authorized to permit the use of byproduct material in medical use;

- c) Before changing the Radiation Safety Officer, except as provided in subsection 335.1040(c);
- d) Before permitting anyone to work as an Associate Radiation Safety Officer or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;
- e) Before receiving radioactive material in excess of the amount, in a different form, or a different radionuclide than is authorized on the license;
- f) Before adding to or changing any area of use identified on the license, including changing the shielding in any area approved on the license. This includes areas used in accordance with Section 335.3010 or 335.4010 if the change includes addition or relocation of an area where PET radionuclides are used, administered, produced, or stored. Other areas of use where radioactive material is used only in accordance with either Section 335.3010 or 335.4010 are exempt;
- g) Before changing the addresses of use identified in the license;
- h) Before changing statements, representations and procedures that are incorporated into the license;
- i) Before receiving a sealed source from a different manufacturer or of a different model number than authorized by the license, unless the sealed source is used for manual brachytherapy, listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART C: GENERAL TECHNICAL REQUIREMENTS

Section 335.2040 Authorization for Calibration, Transmission, Attenuation Correction and Reference Sources

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Any person authorized by Section 335.30 for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration, transmission, attenuation correction and reference use. Reference sources containing radioactive material authorized under this Part shall not be used for medical use except in accordance with the requirements in Section 335.6010. Sealed sources shall not be combined (i.e. bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this Section. Sealed sources are authorized as follows:

- a) Sealed sources not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under 32 Ill. Adm. Code 330.280(k) Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations.
- b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 32 Ill. Adm. Code 330.280(k) Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.
- c) Any radioactive material with a half-life not greater than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).
- d) Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μ Ci) or 1000 times the quantities in Appendix B of 32 Ill. Adm. Code 330.
- e) Technetium-99m in amounts as needed.
- ~~f) Yttrium-90 in individual amounts not to exceed 4.6 GBq (125 mCi).~~
- ~~g) Gadolinium-153 in individual amounts not to exceed 22.2 GBq (600 mCi).~~

(Source: Amended at 47 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

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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: [U.S. Nuclear Regulatory Commission Regulatory Guide 8.39, Rev. 1, "Release of Patients Administered Radioactive Material", published April 2020, NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Licenses," published September 2019,](#) 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).

- 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 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 under Subpart F or H. The authorized user physician shall state in writing that he or she is 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

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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.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 335.2150 Additional Technical Requirements for Intravascular Brachytherapy Units

In addition to other provisions required by this Part, the licensee authorized to use an intravascular brachytherapy unit for medical use shall:

- a) Have a treatment team consisting of, at a minimum, an interventional cardiologist, an authorized user and an authorized medical physicist and that, at a minimum, an interventional cardiologist and an authorized user will be physically present in the treatment suite during all radioactive procedures.

AGENCY NOTE: The requirements of 32 Ill. Adm. Code 401 regarding radiation therapists must also be met.

- b) Independently verify source strength and uniformity. Dwell time at the treatment location must be monitored and recorded. Source uniformity or strength must not differ by more than 10 percent of the expected values.
- c) For devices requiring additional shielding, demonstrate compliance with 32 Ill. Adm. Code 340.210 and 340.310 requirements.
- d) Inspect sealed sources, source trains or ribbons ~~after~~ before each use and ensure sources are removed from service at intervals established by the manufacturer (i.e., confirm that source trains will not be used after the "use by" date, at intervals

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not to exceed 2 months from the date of shipment, or when evidence of degradation is observed, whichever comes first).

- e) Inspect and service devices containing sealed sources at intervals established by the manufacturer, and ensure that maintenance and repair of the device is performed only by the manufacturer or persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such service.
- f) Prohibit cuts, alterations or splicing of the sealed sources, source trains or ribbons, except in situations involving an emergency where the source wire cannot be returned to its normal safe position. If such cuts, alterations or splicing are necessary, notification in accordance with Section 335.1080 or 32 Ill. Adm. Code 340.1220 shall be made to the Agency.
- g) Use only manufacturer provided inducer sheaths, catheters and accessories to ensure their demonstrated equivalents will be used with the devices.
- h) Ensure the daily operational checks will be performed prior to patient treatment. At a minimum, they should include position verification, source uniformity, dwell time function, indicator lamps and other status/operational displays, and visual inspection for integrity of all applicators and catheters to be used for the treatment.
- i) Perform tests following source or device exchange in accordance with the manufacturer's instruction manual for:
 - 1) Timer accuracy/constancy, if appropriate;
 - 2) Calibration of the source output following the manufacturer's instructions; and
 - 3) Interlock/interrupt checks (i.e., interrupt test, cartridge lock test, emergency retraction test and catheter connection test), if appropriate.
- j) The licensee shall retain a record of each item in subsections (b), (d), (e), (h) and (i) for intravascular brachytherapy units for 5 years. The records shall include:
 - 1) The date of the verification, inspection or check.

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- 2) The manufacturer's name, model and serial number of the intravascular brachytherapy unit.
- 3) Results of the verification, inspection or check.
- 4) Notations indicating the operability of each component.
- 5) The identity of the individual who performed the check.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART G: SEALED SOURCES FOR DIAGNOSIS

Section 335.6010 Use of Sealed Sources for Diagnosis

~~A licensee shall use only sealed sources for diagnostic medical uses that are:~~

- a) ~~A licensee shall use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. Obtained from a person specified in Section 335.35, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or~~
- ~~b) Approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.~~
- be) A licensee shall only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance

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with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

- c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Section 335.35 are met.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART H: MANUAL BRACHYTHERAPY

Section 335.7080 Decay of Brachytherapy Sources

- a) Only an ~~authorized medical physicist or physician~~ authorized user qualified under Section 335.9100 or equivalent NRC or Agreement State requirements or an authorized medical physicist shall calculate the activity of each brachytherapy source that is used to determine the treatment times for brachytherapy treatments. The decay must be based on the activity determined under Section 335.7070 of this Part.
- b) A licensee shall maintain a record of the activity of all brachytherapy sources required by this Section for the life of the source. The record must include:
- 1) The manufacturer, model and serial number (or lot number for permanent implants) of the sources;
 - 2) The date and initial activity of the source as determined under Section 335.7070 of this Part; and
 - 3) For each decay calculation, the date and the source activity as determined under this Section.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART I: REMOTE AFTERLOADER UNITS,
TELEETHERAPY UNITS AND
GAMMA STEREOTACTIC RADIOSURGERY UNITS

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

- a) A licensee using sealed sources in remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses shall:
 - 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 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) and the manufacturer's instruction manual shall be physically located at the unit console.
- c) A licensee shall post instructions at the unit console to inform the operator of:
 - 1) The procedures located there as required by subsection (b); and

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- 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.
- d) Operational and Safety Training
 - 1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, the licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.
 - 2) Initially and at least annually, the licensee shall provide operational and safety instructions to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in:
 - A) The procedures identified in subsection (a)(4); and
 - B) 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 instruction required by subsection (d). 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 retain a copy of the procedures required by subsections (a)(4) and (d)(2)(B) 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) for 5 years.

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(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS

Section 335.9010 Training for Radiation Safety Officer and Associate Radiation Safety Officer

Except as provided in Section 335.9160, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer under the requirement in subsection 335.1040(b) to be an individual who:

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

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- A) Hold a master's or doctorate 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 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 or therapeutic services under the direction of physicians who meet the requirements for authorized users in Sections 335.9040, 335.9050 or 335.9160; and
 - iii) Pass an examination administered by diplomates of the specialty board that evaluates knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or
- b) Has successfully completed a structured educational program consisting of both subsections (b)(1) and (b)(2):
 - 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; and
 - E) Radiation dosimetry; and
 - 2) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency,

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U.S. Nuclear Regulatory Commission, or Agreement State license or permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar types and uses of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license or permit issued by a master material licensee. The full-time radiation safety experience shall involve 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; and
- 3) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsections (b)(1), (b)(2) and (f) and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; 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

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335.9150(a) or the U.S. Nuclear Regulatory Commission or an Agreement State and has experience with the radiation safety aspects of similar types of use of radioactive material for which approval of the individual as Radiation Safety Officer or Associate Radiation Safety Officer is sought and meets the requirements in subsection (f); or

- d) Is an authorized user ~~or~~ authorized medical physicist, or authorized nuclear pharmacist identified on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license, 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 an Agreement State licensee of broad scope, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee; has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer; and meets the requirements in subsection (f); or
- e) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license. The individual must also meet the requirements in paragraph (f) of this Section.
- f) Has received training in radiation safety, regulatory issues and emergency procedures for the types of use for which approval is sought. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval.

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

(Source: Amended at 47 Ill. Reg. _____, effective _____)

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

- a) For experienced Radiation Safety Officers and Authorized Medical Physicists:

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- 1) An individual identified as a Radiation Safety Officer or an authorized medical physicist on an Agency, U.S. Nuclear Regulatory Commission or Agreement State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before January 14, 2022 need not comply with the training requirements of Sections 335.9010 and 335.9150, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this subsection shall meet the training requirements in subsections 335.9010(e) and 335.9150(d), as appropriate, for any material or uses for which they were not authorized prior to this date.
- 2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics, the American Board of Radiology, the American Board of Nuclear Medicine, the American Board of Science in Nuclear Medicine, the Board of Pharmaceutical Specialties in Nuclear Pharmacy, the American Board of Medical Physics in radiation oncology physics, the Royal College of Physicians and Surgeons of Canada in nuclear medicine, the American Osteopathic Board of Radiology, or the American Osteopathic Board of Nuclear Medicine on or before October 24, 2007 need not comply with the training requirements of Section 335.9010 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a U.S. Nuclear Regulatory Commission or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2007.
- 3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2007 need not comply with the training requirements for an authorized medical physicist described in Section 335.9150, for those materials and uses that these individuals performed on or before October 24, 2007.

- b) For physicians, dentists or podiatrists:

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- 1) 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, 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 broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2022 who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Sections 335.9030 through 335.9140.
- 2) Physicians, dentists or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Agency, [NRC, U.S. Nuclear Regulatory Commission](#) or Agreement State, a permit issued by ~~the U.S. Nuclear Regulatory Commission master licensee, a permit issued by the a~~ [NRC U.S. Nuclear Regulatory Commission master material licensee, a permit issued by an](#) Agency, [NRC, U.S. Nuclear Regulatory Commission](#) or Agreement State broad scope licensee, or a permit issued ~~in accordance with~~ ~~by~~ a [NRC U.S. Nuclear Regulatory Commission](#) master material ~~broad scope~~ license ~~of broad scope~~ on or before October 24, 2007 need not comply with the training requirements of Sections 335.9030 through 335.9140 for those materials and uses that these individuals performed on or before October 24, 2007, as follows:
 - A) For uses authorized under Section 335.3010, 335.4010, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2007 in nuclear medicine by the American Board of Nuclear Medicine, diagnostic radiology by the American Board of Radiology, diagnostic radiology or radiology by the American Osteopathic Board of Radiology, nuclear medicine by the Royal College of Physicians and Surgeons of Canada, or the American Osteopathic Board of Nuclear Medicine in nuclear medicine;
 - B) For uses authorized under Section 335.5010, a physician who was certified on or before October 24, 2007 by the American Board of Nuclear Medicine; the American Board of Radiology in radiology,

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therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

- C) For uses authorized under Sections 335.7010 and 335.8010, a physician who was certified on or before October 24, 2007 in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and
 - D) For uses authorized under Section 335.6010, a physician who was certified on or before October 24, 2007 in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.
- 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.
 - d) Individuals that qualify under this Section need to comply with Section 335.9180.

(Source: Amended at 47 Ill. Reg. _____, effective _____)