

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

PART 335  
MEDICAL USE OF RADIOACTIVE MATERIAL

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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.

## SUBPART A: GENERAL INFORMATION

### **Section 335.10 Purpose and Scope**

This Part contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. This Part allows use of radioactive material strictly for medical use as authorized by an authorized user and does not allow use for training, demonstration or other purposes unrelated to the treatment of patients. These requirements and provisions provide for the radiation safety of workers, the general public, patients and human research subjects. The requirements of this Part are in addition to, and not in substitution for, others in 32 Ill. Adm. Code: Chapter II, Subchapters b and d. The requirements of 32 Ill. Adm. Code: Chapter II, Subchapters b and d apply to applicants and licensees subject to this Part unless specifically exempted.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.15 Incorporations by Reference**

All rules, standards and guidelines of agencies of the United States or nationally recognized organizations or associations that are incorporated by reference in this Part are incorporated as of the date specified in the reference and do not include any later amendments or editions. Copies of these rules, standards and guidelines that have been incorporated by reference are available for public inspection and copying at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.20 Definitions**

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

"Authorized user" means a physician, dentist or podiatrist who meets the

requirements in Subpart J of this Part or is identified as being authorized to use radioactive material on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by a U.S. Nuclear Regulatory Commission, Agreement State or Licensing State broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

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

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

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

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

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

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

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

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

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

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

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

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

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

"Medical institution" means:

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

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

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

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

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

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

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

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

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

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

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

in a written directive; or

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

"Prescribed dose" means:

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

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

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

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

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

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

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

"Radiation Safety Officer" means an individual who:

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

is identified as a Radiation Safety Officer on:

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

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

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

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

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

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

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

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

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

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

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

(Source: Amended at 32 Ill. Reg. 9247, effective June 13, 2008)

### **Section 335.30 License Required**

- a) A person shall manufacture, produce, acquire, receive, possess, prepare, use or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or as allowed by subsection (b)(1) or (2) of this Section.
- 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 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 unless prohibited by license condition.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

#### **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, except a visiting authorized user described in Section 335.1060 of this Part, to work as an authorized user under the license;
- c) Before changing the Radiation Safety Officer or authorized medical physicist. If the authorized medical physicist named on the license is no longer performing his or her duties, the Radiation Safety Committee may have the duties performed by an individual who is listed by name as an authorized medical physicist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State license, and who meets the training criteria listed in Section 335.9150 of this Part, for up to 90 days while an amendment is being obtained;
- d) Before receiving radioactive material in excess of the amount authorized on the license;
- e) Before adding to or changing any area of use identified on the license, including changing the shielding in any area approved on the license;
- f) Before changing statements, representations and procedures that are incorporated into the license; and
- g) Within 30 days after a Radiation Safety Officer or authorized medical physicist permanently discontinues performance of duties under the license, or after changing the name or the mailing address of the licensee as it appears on the license.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.50 Written Directives (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.60 Provisions for the Protection of Human Research Subjects**

- a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.
- b) If the research is conducted, funded, supported or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:
  - 1) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the Federal Policy; and
  - 2) Obtain informed consent, as defined and described in the Federal Policy, from the human research subject.
- c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:
  - 1) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the Federal Policy; and
  - 2) Obtain informed consent, as defined and described in the Federal Policy, from the human research subject.
- d) Nothing in this Section relieves licensees from complying with the other requirements in this Part.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

#### SUBPART B: GENERAL ADMINISTRATIVE REQUIREMENTS

##### **Section 335.1010 ALARA Program (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

##### **Section 335.1020 Radiation Safety Officer (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

##### **Section 335.1030 Radiation Safety Committee (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.1040 Authorities and Responsibilities for the Radiation Protection Program**

- a) In addition to the radiation protection program requirements of 32 Ill. Adm. Code 340.110, a licensee's management shall approve in writing:
  - 1) Requests for a license application, renewal or amendment before submittal to the Agency.
  - 2) Any individual before allowing that individual to work as an authorized user or authorized medical physicist.
- b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.
- c) A licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under Sections 335.9010, 335.9160, 335.9180 and 335.9190 of this Part, to function as a Radiation Safety Officer designee and to perform the functions of a Radiation Safety Officer, as provided in subsection (g) of this Section, if the licensee takes the actions required in subsections (b), (e), (g), (h) and (i) of this Section.
- d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with subsection (c) of this Section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.
- e) A licensee shall establish the authority, duties and responsibilities of the Radiation Safety Officer in writing.
- f) Licensees that are authorized for two or more different types of uses of radioactive material under Subparts E, F, H and I or Section 335.2140 of this Part for emerging technologies, or two or more types of units under Subpart I of this Part, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized

user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

- g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources and management prerogative to:
  - 1) Identify radiation safety problems;
  - 2) Initiate, recommend or provide corrective actions;
  - 3) Stop unsafe operations; and
  - 4) Verify implementation of corrective actions.
- h) A licensee shall retain a record of actions taken by the licensee's management in accordance with subsection (a) of this Section for 5 years. The record shall include a summary of the actions taken and a signature of licensee's management.
- i) The licensee shall retain a copy of the authority, duties and responsibilities of the Radiation Safety Officer as required by subsection (e) of this Section and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by subsection (b) of this Section, for the duration of the license. The records shall include the signature of the Radiation Safety Officer and licensee's management.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.1050 Supervision**

- a) A licensee who permits the receipt, possession, use or transfer of radioactive material by an individual other than a physician under the supervision of an authorized user as allowed by Section 335.30 of this Part shall:
  - 1) Document instruction provided to the supervised individual, prior to assuming duties requiring the handling of radioactive materials, regarding the principles of radiation safety appropriate to that individual's use of radioactive material;
  - 2) Review the supervised individual's use of radioactive material, provide reinstruction and review records kept to reflect this use;
  - 3) Require the authorized user or Radiation Safety Officer to be available to communicate with the supervised individual; and

- 4) Allow only those individuals who are accredited by the Agency pursuant to 32 Ill. Adm. Code 401.100 or exempt from accreditation by 32 Ill. Adm. Code 401.30, and designated in writing by the licensee, to administer radionuclides or radiation to patients.
- b) A licensee who permits the receipt, possession, use or transfer of radioactive material by a physician under the supervision of an authorized user as allowed by Section 335.30 of this Part shall:
- 1) Review the supervised individual's use of radioactive material, provide reinstruction and review records kept to reflect this use;
  - 2) Require the authorized user to be available to communicate with the supervised individual; and
  - 3) Maintain a record of each supervised individual for a period of 5 years from the initiation of the supervised training. This record shall include the name of each supervised individual, the results of reviews required by subsection (b)(1) of this Section, a description of what procedures the supervised individual is approved to perform and the signature of the supervising authorized user.
- c) A licensee shall require the supervised individual receiving, possessing, using or transferring radioactive material under Section 335.30 of this Part to:
- 1) Follow the instructions of the supervising authorized user;
  - 2) Follow the procedures established by the Radiation Safety Officer; and
  - 3) Comply with this Part and 32 Ill. Adm. Code 310, 330, 340, 341, 400 and 401 and the license conditions with respect to the use of radioactive material.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.1060 Authorized User and Visiting Authorized User**

- a) A licensee shall assure that only authorized users of radioactive material:
- 1) Select or establish written criteria for the selection of the patients to receive radioactive material or radiation therefrom;

- 2) Prescribe the radiopharmaceutical dosage or radiation dose to be administered; and
  - 3) Interpret the results of tests, studies or treatments.
- b) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for up to 60 days each year without applying for a license amendment if:
- 1) The physician is licensed in accordance with the Medical Practice Act of 1987;
  - 2) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;
  - 3) The licensee has a copy of a license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that identifies the visiting authorized user by name as an authorized user; and
  - 4) The visiting authorized user performs only those procedures for which the visiting authorized user is specifically authorized by a license described in subsection (b)(3) of this Section.
- c) A licensee shall retain copies of the records specified in subsection (b) of this Section for 5 years.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.1070 Mobile Nuclear Medicine Service Administrative Requirements (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.1080 Report and Notification of a Medical Event**

- a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:
  - 1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

- A) The total dose delivered differs from the prescribed dose by 20 percent or more;
  - B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
  - C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- 2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:
- A) An administration of a wrong radioactive drug containing radioactive material;
  - B) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
  - C) An administration of a dose or dosage to the wrong individual or human research subject;
  - D) An administration of a dose or dosage delivered by the wrong mode of treatment; or
  - E) A leaking sealed source.
- 3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
  - c) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.
  - d) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

- 1) The written report shall include:
    - A) The licensee's name;
    - B) The name of the prescribing physician;
    - C) A brief description of the event;
    - D) Why the event occurred;
    - E) The effect, if any, on the individual who received the administration;
    - F) What actions, if any, have been taken or are planned to prevent recurrence; and
    - G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, why not.
  - 2) The report may not contain the individual's name or any other information that could lead to identification of the individual.
- e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- f) Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to

individuals affected by the medical event, or to those individuals' responsible relatives or guardians.

- g) A licensee shall:
  - 1) Annotate a copy of the report provided to the Agency with the:
    - A) Name of the individual who is the subject of the event; and
    - B) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
  - 2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.
- h) A licensee shall report to the Agency immediately upon discovery of any irregularities pertaining to identification, labeling, quality or assay of any radiopharmaceutical received under the authority of the license.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.1090 Materials Authorized for Medical Use (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.1100 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child**

- a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- b) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:
  - 1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or
  - 2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

- c) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (a) or (b) of this Section.
- d) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (a) or (b) of this Section.
  - 1) The written report shall include:
    - A) The licensee's name;
    - B) The name of the prescribing physician;
    - C) A brief description of the event;
    - D) Why the event occurred;
    - E) The effect, if any, on the embryo/fetus or the nursing child;
    - F) What actions, if any, have been taken or are planned to prevent recurrence; and
    - G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, why not.
  - 2) The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.
- e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subsection (a) or (b) of this Section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection (e), the notification may be made to the mother's or child's responsible relative or guardian instead of the mother.

If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide a written description if requested.

- f) A licensee shall:
  - 1) Annotate a copy of the report provided to the Agency with the:
    - A) Name of the pregnant individual or the nursing child who is the subject of the event; and
    - B) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
  - 2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.1110 Written Directives**

- a) A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq (30  $\mu$ Ci), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours after the oral directive.
- b) The written directive shall contain the patient's or human research subject's name and the following information:
  - 1) For any administration of quantities greater than 1.11 MBq (30  $\mu$ Ci) of sodium iodide I-131, the dosage.
  - 2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131, the radioactive drug, dosage and route of administration.

- 3) For gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.
- 4) For teletherapy, the total dose, dose per fraction, number of fractions and treatment site.
- 5) For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions and total dose.
- 6) For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:
  - A) Before implantation, treatment site, the radionuclide and dose; and
  - B) After implantation but before completion of the procedure, the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).
- c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours after the oral revision.
- d) A licensee shall retain a copy of each written directive as required by subsections (a) and (c) of this Section for 5 years.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.1120 Procedures for Administrations Requiring a Written Directive**

- a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
  - 1) The patient's or human research subject's identity is verified before each administration; and

- 2) Each administration is in accordance with the written directive.
- shall
- b) At a minimum, the procedures required by subsection (a) of this Section address the following items that are applicable to the licensee's use of radioactive material:
- 1) Verifying the identity of the patient or human research subject;
- 2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- and
- 3) Checking both manual and computer-generated dose calculations;
- 4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 335.8010 of this Part.
- c) A licensee shall retain a copy of the procedures required by subsection (a) of this Section for the duration of the license.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

#### SUBPART C: GENERAL TECHNICAL REQUIREMENTS

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

- a) For licensees performing direct measurements, the licensee shall possess and use appropriate instrumentation to measure the radioactivity of radiopharmaceuticals.
- b) Perform tests on each instrument for constancy, accuracy, linearity and geometry dependence, in accordance with nationally recognized standards or the manufacturer's instructions.
- c) A licensee shall maintain a record of instrument calibrations required by subsection (b) of this Section for 5 years. The records shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration, the name of the individual who performed the calibration and a copy of the national standard or manufacturer's instructions used to perform the calibration.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.2020 Possession, Calibration and Check of Survey Instruments  
(Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**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
  - 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 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or
    - B) An Agency, U.S. Nuclear Regulatory Commission or Agreement 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 of measurement of radioactivity and mathematical calculations; or
  - 3) A combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement 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:
  - 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 35 Ill. Reg. 884, effective December 30, 2010)

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

Any person authorized by Section 335.30 of this Part for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration, transmission, attenuation correction and reference use:

- a) Sealed sources not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Section 335.30 of this Part 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 Section 335.30 of this Part,

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  $\mu$ 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 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.2050 Requirements for Possession of Sealed Sources (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.2060 Labeling and Use of Vials and Syringes**

- a) Each syringe and vial that contains unsealed radioactive material shall be labeled to identify the radiopharmaceutical. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.
- b) A licensee shall use syringe radiation shields unless the use of a shield is contraindicated for an individual patient.

AGENCY NOTE: The use of a syringe radiation shield could be contraindicated if a patient presented a venous anatomy poorly suited for venipuncture.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.2070 Vial Shields and Vial Shield Labels (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

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

- a) In addition to the monitoring required by 32 Ill. Adm. Code 340, the

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

- b) At least once each week, a licensee shall measure with a radiation measurement instrument capable of measuring dose rates over the range 10 $\mu\text{Sv}$ (1 mrem) per hour to 10 mSv (1 rem) per hour all areas where radiopharmaceuticals or radioactive wastes are stored to ensure compliance with 32 Ill. Adm. Code 340.210 and 340.310. The instrument shall be operable and calibrated in accordance with the requirements of 32 Ill. Adm. Code 340.510(b) and (c).
- c) At least once each week, a licensee shall measure for removable contamination in all areas where unsealed radioactive materials are prepared for use, administered or stored.
- d) A licensee shall conduct the measurements required by subsections (b) and (c) of this Section in a manner that permits detection of contamination on each wipe sample of 2000 dpm per 100 square centimeters of surface area.
- e) A licensee shall retain a record of all monitoring and surveys required by this Section for 5 years. The record shall include the monitoring date, a sketch of each area monitored, the measured dose rate at several points in each area expressed in units, multiples or subunits of sieverts or rem per hour or the removable contamination in each area expressed in units, multiples or subunits of becquerels or curies per 100 square centimeters of surface area or in disintegrations (transformations) per minute per 100 square centimeters of surface area, the manufacturer, model and serial number of the instrument used to perform the monitoring or analyze the samples and the identity of the individual who performed the monitoring.

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

(Source: Amended at 32 Ill. Reg. 9247, effective June 13, 2008)

**Section 335.2090 Safety Instructions for Patients Not Hospitalized and Containing Therapeutic Doses of Radiopharmaceuticals or Permanent Implants (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.2100 Admission of Patients Being Treated with Radiopharmaceuticals or Permanent Implants (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**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).

- 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 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 35 Ill. Reg. 884, effective December 30, 2010)

### **Section 335.2120 Mobile Medical Service Requirements**

A licensee providing mobile medical service shall:

- a) Prior to bringing radioactive material into a remote use location, obtain a letter, signed by the management of the client for whom services are rendered, that clearly delineates the authority and responsibility of the licensee and the client and authorizes use of radioactive material at the client's address of use.
- b) Transport to each address of use only those syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits.
- c) Provide services in accordance with the client's specific medical license, when providing services that the client is also authorized to provide.
- d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this subsection shall include a constancy check.
- e) Before releasing a use location for unrestricted use, monitor all areas of use with a radiation detection survey instrument to ensure that all

radioactive materials and all associated radioactive wastes have been removed.

AGENCY NOTE: 32 Ill. Adm. Code 340, Appendix A may be used as a guideline for this purpose.

- f) Check survey instruments for proper operation with a dedicated check source before use at each client's address.
- g) Secure or keep under constant surveillance and control all radioactive material when in transit and at a location of use.
- h) Not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.
- i) Retain the letter required in subsection (a) of this Section and the record of monitoring required in this Section in accordance with Section 335.2080(e) of this Part.
- j) Retain a copy of each letter that permits the use of radioactive material at a client's address as required by subsection (a) of this Section. Each letter must clearly delineate the authority and responsibility of the licensee and the client and shall be retained for 5 years after the last provision of service.
- k) Retain the record of monitoring required by subsection (e) of this Section for 5 years. The record shall include the monitoring date, an annotated diagram of each area that was monitored, the measured dose rate at several points in each area of use expressed in units, multiples or subunits of Sieverts (or rem) per hour, the manufacturer, model and serial number of the instrument used to perform the monitoring and the identity of the individual who performed the monitoring.
- l) Retain a record of all dosages administered under the service's license for 5 years after the date of administration. This record shall include the radiopharmaceutical name, the clinical procedure, the activity administered, the name of the authorized user, the date of administration and the identity of the individual performing the administration.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.2130 Storage of Volatiles and Gases (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.2140 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (Emerging Technologies)**

A licensee may use radioactive material or a radiation source that is not specifically addressed in Subparts D through I of this Part, or if the use is inconsistent with those Subparts, if:

- a) The licensee has submitted the information required by 32 Ill. Adm. Code 330.250 and any other necessary information consistent with 32 Ill. Adm. Code 330;
- b) The application contains at least the following:
  - 1) A request signed by management that is consistent with the requirements of 32 Ill. Adm. Code 340.310(b);
  - 2) A description of:
    - A) The facilities, with a diagram;
    - B) The necessary equipment and its calibration or maintenance; and
    - C) Training and experience qualifications of the Radiation Safety Officer, authorized users and authorized medical physicists, if not already previously submitted;
  - 3) Procedures, as applicable, that describe:
    - A) The radionuclide, form and activity;
    - B) The expected levels of contamination and the procedures to control them;
    - C) The general safety precautions;
    - D) The safety instructions to be provided to staff that are specific to the proposed use; and
    - E) The methodology for measurement of dosages or doses to be administered to patients or human research subjects;
  - 4) If applicable, a description of the sealed source and/or device as per 32 Ill. Adm. Code 330.280(i) and (k), as applicable, or,

alternately, identification of the product in the Sealed Source and Device Registry.

- c) In addition to the requirements in subsection (b)(2) of this Section, an application for a license or amendment for medical use of radioactive material as described in this Section shall also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this Part.
- d) The applicant or licensee has provided any other information requested by the Agency in its review of the application.
- e) The licensee has received written approval from the Agency in the form of a license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the safe use of the material.

AGENCY NOTE: The FDA accepted protocols may be submitted as partial application towards the information requested in this Section.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

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

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

Except for quantities that require a written directive under subsection 335.1110(a), 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, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or
- b) Excluding production of PET radionuclides, 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 Section 335.9050 and subsection 335.9040(c)(1)(B)(vii) or an individual under the supervision of either as specified in Section 335.1050; or
- c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or Agreement 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 35 Ill. Reg. 884, effective December 30, 2010)

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

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

Except for quantities that require a written directive under subsection 335.1110(a), 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 requirements; or
- b) Excluding production of PET radionuclides, 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) or an individual under the supervision of either as specified in Section 335.1050; or
- c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or Agreement 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 35 Ill. Reg. 884, effective December 30, 2010)

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

- a) A licensee shall not administer to humans a radiopharmaceutical that contains more than:
- 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) 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 concentration tests required by subsection (b) of this Section for 5 years. The record shall include for each measurement, the time and date of the measurement, 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 a concentration exceeding the limits specified in subsection (a) of this Section.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

### **Section 335.4030 Control of Aerosols and Gases (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

SUBPART F: UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE  
REQUIRED

**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 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements;
- b) Excluding production of PET radionuclides, 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) or an individual under the supervision of either as specified in Section 335.1050; or
- c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or Agreement 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 35 Ill. Reg. 884, effective December 30, 2010)

**Section 335.5020 Safety Instruction**

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

- a) A licensee shall provide 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 be commensurate with the duties of the personnel and shall include:
  - 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 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 35 Ill. Reg. 884, effective December 30, 2010)

### **Section 335.5030 Safety Precautions**

- a) For each patient or human research subject who cannot be released under Section 335.2110 of this Part, the licensee shall:
- 1) Perform radiation monitoring as required by 32 Ill. Adm. Code 340.510 for use in determining when the licensee shall supply appropriate personnel with individual monitoring devices as required by 32 Ill. Adm. Code 340.520. Records of the radiation monitoring indicating the date and time of the monitoring, an annotated diagram of the area and a list of points monitored, the measured dose rate, the manufacturer, model and serial number of the instrument used to perform the monitoring and the identity of the individual who performed the monitoring shall be maintained for 5 years. This radiation monitoring shall include, as a minimum, the dose rate in units, multiples or subunits of Sieverts or rem per hour at:
    - A) The patient's bedside;
    - B) 1 meter from the patient;
    - C) The patient's hospital room door; and
    - D) Contiguous restricted and unrestricted areas. However, radiation monitoring of adjoining rooms is not required if a calculation of the dose rate to a patient in the adjoining room is made based on measurements obtained pursuant to subsection (a)(1)(A) or (B) of this Section.

- 2) Prevent any patient who is not receiving radiopharmaceutical therapy, but who is occupying a room that adjoins the room of a patient who is receiving radiopharmaceutical therapy, to receive a dose greater than 1 mSv (100 mrem) during the patient's entire stay from radiation emitted by any therapy patient. The licensee shall verify compliance by performing radiation surveys based on the monitoring required by subsection (a)(1) of this Section.
- 3) Prevent the placement of a therapy patient in the same room with a patient who is not receiving radiopharmaceutical therapy unless the licensee demonstrates, by monitoring or surveys, compliance with the requirements of 32 Ill. Adm. Code 340.310 at a distance of 1 meter from the therapy patient.
- 4) Provide each therapy patient's room with a private sanitary facility.
- 5) Post the patient's door with a "Caution: Radioactive Materials" sign. The posted sign shall indicate that pregnant women, or women who suspect that they are pregnant, shall contact the attendant staff for additional safety instructions or precautions. Also, a note shall appear on the door and on the patient's chart which states where and how long visitors may stay in the patient's room.
- 6) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the radiation therapy physician after consultation with the Radiation Safety Officer.
- 7) Maintain and make available nursing instructions for the attendant nursing staff that list any restrictions and instructions that shall be followed regarding the care of therapy patients.
- 8) Either monitor all items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding other than a plastic or cloth bag or handle all items removed from the patient's room as radioactive waste.
- 9) Advise attendant nursing staff to notify the Radiation Safety Officer or the radiation therapy physician immediately if the therapy patient dies or has a medical emergency.
- 10) Monitor the patient's room and sanitary facility for removable contamination. The room shall not be re-assigned until the requirements of 32 Ill. Adm. Code 340.320 and 340.510 have been

met.

- b) The licensee shall implement the precautions required by subsections (a)(1) through (10) of this Section until all of the requirements of Section 335.2110 of this Part can be met.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### 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) Obtained from a person specified in Section 335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or
- b) Approved and used in accordance with the Sealed Source and Device Registry and the manufacturer's instruction manual.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### SUBPART H: MANUAL BRACHYTHERAPY

##### **Section 335.7010 Use of Sealed Sources for Manual Brachytherapy**

A licensee shall use only brachytherapy sources for therapeutic medical uses:

- a) That are:
  - 1) Obtained from a person specified in Section 335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; and
  - 2) Approved and used in accordance with the Sealed Source and Device Registry and the manufacturer's instruction manual; or
- b) That are used in research in accordance with an active protocol accepted by the FDA provided the requirements of Section 335.30 of this Part are met.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

##### **Section 335.7020 Safety Instruction**

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

- a) The licensee shall provide radiation safety instruction, prior to their assuming duties and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under Section 335.2110 of this Part. To satisfy this requirement, the instructions must be commensurate with the duties of the personnel and include the:
  - 1) Size and appearance of the brachytherapy sources;
  - 2) Safe handling and shielding instructions;
  - 3) Patient or human research subject control;
  - 4) Visitor control, including both:
    - A) Routine visitation of 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); and
  - 5) Notification of the Radiation Safety Officer, or his or her designee, and an 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 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 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.7030 Safety Precautions**

- a) For each patient or human research subject who is receiving brachytherapy and cannot be released under Section 335.2110 of this Part, a licensee shall:
  - 1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;
  - 2) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

- 3) Conspicuously post the patient's or human research subject's room with a "Caution – Radioactive Materials" sign bearing the radiation symbol;
  - 4) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and
  - 5) Note on the door or in the patient's or human research subject's chart safety instruction noted in Section 335.7020 of this Part.
- b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
- 1) Dislodged from the patient; and
  - 2) Lodged within the patient following removal of the source applicators.
- c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

#### **Section 335.7040 Accountability and Security of Brachytherapy Sources**

- a) A licensee shall maintain security and accountability at all times for all brachytherapy sources in storage or use.
- b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.
- c) A licensee shall maintain a record of brachytherapy source accountability required by this Section for 5 years. The record must include:
  - 1) For temporary implants:
    - A) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage and the location of use; and

- B) The number and activity of sources returned to storage, the time and date they were returned to storage and the name of the individual who returned them to storage.
- 2) For permanent implants:
- A) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
  - B) The number and activity of sources not implanted, the date they were returned to storage and the name of the individual who returned them to storage; and
  - C) The number and activity of sources permanently implanted in the patient or human research subject.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.7050 Discharge of Patients Treated With Temporary Implants (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.7060 Surveys After Source Implant and Removal**

- a) Immediately after implanting sources in a patient or a human research subject, the licensee shall monitor the area to locate and account for all sources that have not been implanted.
- b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall monitor the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.
- c) A licensee shall maintain a record of the monitoring required by this Section for 5 years. The record shall include the monitoring date, the measured dose rate at several points in each area, expressed in units, multiples or subunits of Sieverts or rem per hour, the manufacturer, model and serial number of the survey instrument used to perform the monitoring, and the identity of the person who performed the monitoring.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.7070 Calibration Measurements of Brachytherapy Sources**

- a) Before the first medical use of a brachytherapy source on or after October 24, 2006, a licensee shall have:
  - 1) Determined the source output or activity using a dosimetry system that meets the requirements of Section 335.8080 of this Part;
  - 2) Determined source positioning accuracy within applicators; and
  - 3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subsections (a)(1) and (a)(2) of this Section. Copies of these protocols shall be maintained on file by the licensee for 5 years after the discontinuation of use of brachytherapy sources.
- b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine or other calibration laboratory approved by the Agency that are made in accordance with subsection (a) of this Section.
- c) A licensee shall mathematically correct the outputs or activities determined in subsection (a) of this Section for physical decay at intervals consistent with 1 percent physical decay.
- d) A licensee shall maintain a record of the calibrations of brachytherapy sources required by this Section for 5 years after the last use of the source. The record must include:
  - 1) The date of the calibration;
  - 2) The manufacturer's name, model, and serial number for the source, and the instruments used to calibrate the source;
  - 3) The source output or activity;
  - 4) The source positioning accuracy within the applicators; and
  - 5) The signature of the authorized medical physicist.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.7080 Decay of Brachytherapy Sources**

- a) Only an authorized medical physicist or physician-authorized user 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: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.7090 Therapy-related Computer Systems for Manual Brachytherapy**

The licensee shall:

- a) Perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:
  - 1) The source-specific input parameters required by the dose calculation algorithm;
  - 2) The accuracy of dose, dwell time, and treatment time calculations at representative points;
  - 3) The accuracy of isodose plots and graphic displays; and
  - 4) The accuracy of the software used to determine sealed source positions from radiographic images.
- b) Maintain a record of acceptance testing and copies of the protocols used for acceptance testing in accordance with this Section for 5 years after discontinuation of use of the treatment planning system.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

### **SUBPART I: REMOTE AFTERLOADER UNITS, INTRAVASCULAR BRACHYTHERAPY UNITS, THERAPY 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**

A licensee shall use sealed sources in remote afterloader units, intravascular brachytherapy units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses that are:

- a) Obtained from a person specified in Section 335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission, Agreement State or Licensing State requirements; or
- b) Approved and used in accordance with the Sealed Source and Device Registry and the manufacturer's instruction manual; or
- c) Used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of Section 335.30 of this Part are met.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8020 Installation, Maintenance, Adjustment and Repair Restrictions**

- a) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State shall install, maintain, adjust or repair a remote afterloader unit, intravascular brachytherapy unit, teletherapy unit or gamma stereotactic radiosurgery unit that involves work on the sources shielding, the sources driving unit or other electronic or mechanical component that could expose the sources, reduce the shielding around the sources, or compromise the radiation safety of the unit or the sources.
- b) Except for a low dose-rate remote afterloader unit and intravascular brachytherapy unit, only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, intravascular brachytherapy units, teletherapy units or gamma stereotactic radiosurgery units.
- c) For a low dose-rate remote afterloader unit and intravascular brachytherapy unit, only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State or an authorized medical physicist shall install, replace, relocate or remove a sealed source contained in the unit.

- d) A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, intravascular brachytherapy units, teletherapy units and gamma stereotactic radiosurgery units as required by this Section for 5 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, names of the individuals who performed the work, and a copy of the specific license authorizing the service.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8030 Amendments to Teletherapy Licenses (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

### **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:
  - 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) of this Section 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) 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.
- 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 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 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 35 Ill. Reg. 884, effective December 30, 2010)

**Section 335.8050 Safety Precautions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units**

- a) A licensee shall control access to the treatment room by a door at each entrance.
- b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that shall:
  - 1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
  - 2) Cause the sources to be shielded when an entrance door is opened; and
  - 3) Prevent the sources from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sources on-off control is reset at the console.
- c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.
- f) In addition to the requirements specified in subsections (a) through (e) of this Section, a licensee shall:
  - 1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:
    - A) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation of, and emergency response for, the unit to be physically present during the initiation of all patient treatments involving the unit; and

- B) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicators in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
- 2) For high dose-rate remote afterloader units, require:
    - A) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
    - B) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
  - 3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
  - 4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
- g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
    - 1) Remaining in the unshielded position; or
    - 2) Lodged within the patient following completion of the treatment.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8060 Radiation Monitoring Device for Teletherapy Units and Gamma Stereotactic Radiosurgery Units**

- a) A licensee shall have in each teletherapy or gamma stereotactic radiosurgery room a permanent radiation monitor capable of continuously monitoring the status of the beam.
- b) Each radiation monitor shall be capable of providing visible indication of a teletherapy or gamma stereotactic radiosurgery unit malfunction that

results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy or gamma stereotactic radiosurgery room.

- c) Each radiation monitor shall be equipped with an auxiliary power supply separate from the power supply to the teletherapy or gamma stereotactic radiosurgery unit. This auxiliary power supply may be a battery system.
- d) The radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy or gamma stereotactic radiosurgery unit is used for treatment of patients.

AGENCY NOTE: Exposing the source and remotely viewing the instrument response is an acceptable method for checking the monitor with a "dedicated check source".

- e) A licensee shall maintain a record of the check required by subsection (d) of this Section for 5 years. The record shall include the date of the check, a notation that the monitor indicated when the source was exposed and the identity of the individual who performed the check.
- f) If the radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy or gamma stereotactic radiosurgery room to use either a survey instrument or a personal dosimeter with an audible alarm to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subsection (e) of this Section.
- g) If the radiation monitor is inoperable, the licensee shall take action within 24 hours to repair or replace the radiation monitor. At a minimum, such action shall include the scheduling for the repair or replacement of the inoperable monitor.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8070 Viewing System for Teletherapy (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8080 Dosimetry Equipment**

- a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

- 1) The system shall have been calibrated by the National Bureau of Standards, by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
  - 2) The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been compared with another dosimetry system that was calibrated within the past 24 months by the National Bureau of Standards, by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The dosimetry system shall be considered calibrated if a comparison is performed at a meeting sanctioned by a calibration laboratory or radiological physics center accredited by the AAPM and the results of the comparison indicate that the calibration factor of the licensee's system has not changed by more than two percent. The licensee shall not use the comparison result to change the calibration factor. When comparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.
- b) The licensee shall have available for use a calibrated dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subsection (a) of this Section. This comparison shall have been performed within the previous year and after each servicing that may have affected calibration of the calibrated system. The spot-check system may be the same system used to meet the requirements in subsection (a) of this Section.
- c) The licensee shall retain a record of each calibration and comparison for the duration of the license. For each calibration or comparison, the record shall include the date, the manufacturer, the model and serial number of the instruments that were calibrated or compared as required by subsections (a) and (b) of this Section, the correction factors that were deduced, the names of the individuals who performed the calibration or comparison and evidence that the comparison meeting was sanctioned by a calibration laboratory or radiological physics center accredited by AAPM.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8090 Full Calibration Measurements for Teletherapy**

- a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements as described in subsection (b) of this Section, on each teletherapy unit:
  - 1) Before the first medical use of the unit; and
  - 2) Before medical use under the following conditions:
    - A) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration, corrected mathematically for radioactive decay;
    - B) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
    - C) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
  - 3) At intervals not exceeding 1 year.
- b) To satisfy the requirement of subsection (a) of this Section, full calibration measurements shall include determination of:
  - 1) The output, within three percent, for the range of field sizes and for the distance or range of distances used for medical use;
  - 2) The coincidence of the radiation field and the field indicated by the light beam localizing device;
  - 3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
  - 4) Timer constancy and linearity over the range of use;
  - 5) On-off error; and
  - 6) The accuracy of all distance measuring and localization devices in medical use.
- c) A licensee shall use the dosimetry system described in Section 335.8080

of this Part to measure the output for one set of exposure conditions. The remaining radiation measurements required by subsection (b)(1) of this Section may then be made using a dosimetry system that indicates relative dose rates.

- 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) A licensee shall mathematically correct for physical decay the outputs determined in subsection (b)(1) of this Section. These corrections shall be for intervals not exceeding 1 month for cobalt-60 and intervals not exceeding 6 months for cesium-137 or at intervals consistent with 1 percent decay for all other nuclides.
- f) Full calibration measurements required by subsection (a) of this Section and physical decay corrections required by subsection (e) of this Section shall be performed by an authorized medical physicist.
- g) A licensee shall retain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model and serial numbers for both the teletherapy unit and the source, the model and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distance used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer constancy and linearity, the calculated on-off error, the determined accuracy of each distance measuring or localization device and the signature or initials of the authorized medical physicist.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8100 Periodic Spot-Checks for Teletherapy**

- a) A licensee authorized to use teletherapy units for medical use shall perform spot-checks on each teletherapy unit at intervals not to exceed 1 month.
- b) To satisfy the requirement of subsection (a) of this Section, spot-checks shall include the taking of measurements that permit the determination of:
  - 1) Timer constancy and linearity over the range of use;
  - 2) On-off error;

- 3) The coincidence of the radiation field and the field indicated by the light beam localization device;
  - 4) The accuracy of all distance measuring and localization devices used for medical use;
  - 5) The output for one typical set of operating conditions; and
  - 6) The difference between the measurement made in subsection (b)(5) of this Section and the anticipated output, expressed as a percentage of the anticipated value obtained at the last full calibration corrected mathematically for physical decay.
- c) A licensee shall use the dosimetry system described in Section 335.8080 of this Part to make the measurement required in subsection (b)(5) of this Section.
- d) A licensee shall perform measurements required by subsection (a) of this Section in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist does not need to actually perform the spot-check measurements.
- e) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall, within 15 days, notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 5 years.
- f) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed 1 month. To satisfy this requirement, checks shall assure proper operation of:
- 1) Electrical interlocks at each teletherapy room entrance;
  - 2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (i.e., restriction of source housing angulation or elevation, carriage or stand travel, operation of the beam on-off mechanism);
  - 3) Beam condition indicator lights on the teletherapy unit, on the control console and in the facility;
  - 4) Viewing systems;
  - 5) Treatment room doors from inside and outside the treatment room;

and

- 6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- g) If the results of the checks required in subsection (f) of this Section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.
- h) A licensee shall retain a record of each spot-check required by subsections (a) and (f) of this Section for 5 years. The record shall include the date of the spot-check, the model and serial number for both the teletherapy unit and source, the model and serial number of the instrument used to measure the output of the teletherapy unit, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer constancy and linearity, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the identity of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8110 Radiation Monitoring**

- a) In addition to the monitoring requirements in 32 Ill. Adm. Code 340.510, a person licensed under this Subpart shall monitor to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
- b) The licensee shall monitor, as required by subsection (a) of this Section, at installations of a new source and following repairs to the source's shielding, the source's driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.
- c) A licensee shall maintain a record of the radiation monitoring of treatment units made in accordance with this Section for the duration of use of the unit. The record must include:
  - 1) The date of the measurement;

- 2) The manufacturer's name, model and serial number of the treatment unit, source and instrument used to measure radiation levels;
- 3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
- 4) The signature of the individual who performed the test.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8120 Safety Checks for Teletherapy Facilities (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8130 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8140 Reports of Teletherapy Monitoring, Checks, Tests and Measurements (Repealed)**

(Source: Repealed at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8150 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units**

- a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
- b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.
- c) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by this Section for the duration of use of the unit.
- d) The record must contain:
  - 1) The inspector's radioactive materials license number;

- 2) The date of the inspection;
  - 3) The manufacturer's name and model and serial number of both the treatment unit and source;
  - 4) A list of components inspected, services and the type of service;
- and
- 5) The signature of the inspector.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

**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;
  - 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 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 335.8080(a) to measure the output.
  - 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 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 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 unit, together with the sources and the instruments used to calibrate it;
    - 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
- 5) The signature of the authorized medical physicist who performed the full calibration.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

**Section 335.8170 Periodic Spot-Checks for Remote Afterloader Units**

- a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
  - 1) Before the first use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit on a given day;
  - 2) Before each patient treatment with a low dose-rate remote afterloader unit; and
  - 3) After each source installation.
- b) A licensee shall perform the measurements required by subsection (a) of this Section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.
- c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- d) To satisfy the requirements of subsection (a) of this Section, spot-checks must, at a minimum, assure proper operation of:
  - 1) Electrical interlocks at each remote afterloader unit room entrance;
  - 2) Source exposure indicator lights on the remote afterloader unit, on the control console and in the facility;
  - 3) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
  - 4) Emergency response equipment;
  - 5) Radiation monitors used to indicate the source position;

- 6) Timer accuracy;
  - 7) Clock (date and time) in the unit's computer; and
  - 8) Decayed sources activity in the unit's computer.
- e) If the results of the checks required in subsection (d) of this Section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.
- f) A licensee shall retain a record of each spot-check for remote afterloader units required by this Section for 5 years.
- g) The record must include, as applicable:
- 1) The date of the spot-check;
  - 2) The manufacturer's name, model and serial number for the remote afterloader unit and source;
  - 3) An assessment of timer accuracy;
  - 4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems and clock and decayed source activity in the unit's computer; and
  - 5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.
- h) A licensee shall retain a copy of the procedures required by subsection (b) of this Section until the licensee no longer possesses the remote afterloader unit.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8180 Monitoring of Patients and Human Research Subjects Treated with a Remote Afterloader Unit or Intravascular Brachytherapy Unit**

- a) Before releasing a patient or a human research subject from licensee control, a licensee shall monitor the patient or the human research subject and the remote afterloader or intravascular brachytherapy unit with a portable radiation detection survey instrument to confirm that the sources

have been removed from the patient or human research subject and returned to the safe shielded position.

- b) A licensee shall maintain a record of the monitors required by this Section for 5 years. Each record must include the date and results of the monitoring, the manufacturer, model and serial numbers of the survey instrument used and the name of the individual who performed the monitoring.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8190 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units**

- a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
  - 1) Before the first medical use of the unit;
  - 2) Before medical use under the following conditions:
    - A) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
    - B) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
    - C) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
  - 3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.
- b) To satisfy the requirement of subsection (a) of this Section, full calibration measurements must include determination of:
  - 1) The output within  $\pm 3$  percent;
  - 2) Relative helmet factors;

- 3) Isocenter coincidence;
  - 4) Timer accuracy and linearity over the range of use;
  - 5) On-off error;
  - 6) Trunnion centricity;
  - 7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
  - 8) Helmet microswitches;
  - 9) Emergency timing circuits; and
  - 10) Stereotactic frames and localizing devices (trunnions).
- c) A licensee shall use the dosimetry system described in Section 335.8080(a) of this Part to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (b)(1) of this Section may be made using a dosimetry system that indicates relative dose rates.
  - 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) A licensee shall mathematically correct the outputs determined in subsection (b)(1) of this Section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.
  - f) Full calibration measurements required by subsection (a) of this Section and physical decay corrections required by subsection (e) of this Section must be performed by the authorized medical physicist.
  - g) A licensee shall maintain a record of the gamma stereotactic radiosurgery unit full calibrations required by this Section for 5 years.
  - h) The record must include:
    - 1) The date of the calibration;
    - 2) The manufacturer's name, model and serial number of the gamma stereotactic radiosurgery units, the sources, and the instruments used to calibrate the units;

- 3) The results and an assessment of the full calibrations; and
- 4) The signature of the authorized medical physicist who performed the full calibration.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8200 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units**

- a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:
  - 1) Monthly;
  - 2) Before the first use of the unit on a given day; and
  - 3) After each source installation.
- b) A licensee shall:
  - 1) Perform the measurements required by subsection (a) of this Section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.
  - 2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- c) To satisfy the requirements of subsection (a)(1) of this Section, spot-checks must, at a minimum:
  - 1) Assure proper operation of:
    - A) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
    - B) Helmet microswitches;
    - C) Emergency timing circuits; and
    - D) Stereotactic frames and localizing devices (trunnions).

- 2) Determine:
  - A) The output for one typical set of operating conditions measured with the dosimetry system described in Section 335.8080(b) of this Part;
  - B) The difference between the measurement made in subsection (c)(2)(A) of this Section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
  - C) Source output against computer calculation;
  - D) Timer accuracy and linearity over the range of use;
  - E) On-off error; and
  - F) Trunnion centricity.
- d) To satisfy the requirements of subsections (a)(2) and (a)(3) of this Section, spot-checks must assure proper operation of:
  - 1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
  - 2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console and in the facility;
  - 3) Viewing and intercom systems;
  - 4) Timer termination;
  - 5) Radiation monitors used to indicate room exposures; and
  - 6) Emergency off buttons;
- e) A licensee shall arrange for the repair of any system identified in subsection (c) of this Section that is not operating properly as soon as possible.
- f) If the results of the checks required in subsection (d) of this Section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

- g) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by this Section for 5 years.
- 1) The record must include:
    - A) The date of the spot-check;
    - B) The manufacturer's name, model and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
    - C) An assessment of timer linearity and accuracy;
    - D) The calculated on-off error;
    - E) A determination of trunnion centricity;
    - F) The difference between the anticipated output and the measured output;
    - G) An assessment of source output against computer calculations;
    - H) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
    - I) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.
  - 2) A licensee shall retain a copy of the procedures required by subsection (b) of this Section until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8210 Additional Technical Requirements for Mobile Remote Afterloader Units**

- a) A licensee providing mobile remote afterloader service shall:

- 1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
  - 2) Account for all sources before departure from a client's address of use.
- b) In addition to the periodic spot-checks required by Section 335.8170 of this Part, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
- 1) Electrical interlocks on treatment area access points;
  - 2) Source exposure indicator lights on the remote afterloader unit, on the control console and in the facility;
  - 3) Viewing and intercom systems;
  - 4) Applicators, source transfer tubes and transfer tube-applicator interfaces;
  - 5) Radiation monitors used to indicate room exposures;
  - 6) Source positioning (accuracy); and
  - 7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.
- c) In addition to the requirements for checks in subsection (b) of this Section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
- d) If the results of the checks required in subsections (b) and (c) of this Section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.
- e) A licensee shall retain a record of each check for mobile remote afterloader units required by this Section for 5 years.
- f) The record must include:
- 1) The date of the check;

- 2) The manufacturer's name, model and serial number of the remote afterloader unit;
- 3) Notations accounting for all sources before the licensee departs from a facility;
- 4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, transfer tube applicator interfaces, and source positioning accuracy; and
- 5) The signature of the individual who performed the check.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

### **Section 335.8220 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 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 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 is necessary, notification in accordance with Section 335.1080 of this Part or 32 Ill. Adm. Code 340.1220 must 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) of this Section for intravascular brachytherapy units for 5 years. The records must include:
  - 1) The date of the verification, inspection or check.
  - 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 signature of the individual who performed the check.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

**Section 335.8230 Therapy-related Computer Systems for Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Units**

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- a) The source-specific input parameters required by the dose calculation algorithm;
- b) The accuracy of dose, dwell time and treatment time calculations at representative points;
- c) The accuracy of isodose plots and graphic displays;
- d) The accuracy of the software used to determine sealed source positions from radiographic images; and
- e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(Source: Added at 30 Ill. Reg. 9029, effective April 28, 2006)

**SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS**

**Section 335.9010 Radiation Safety Officer**

Except as provided in Section 335.9160, the licensee shall require an individual fulfilling the responsibilities of the 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 has obtained the attestation and training described in subsections (e) and (f) of this Section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:
  - 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 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:
- 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 diplomate of the specialty board that evaluates 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. 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 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 and has experience in radiation safety for similar types of use of radioactive material for which approval of the individual as Radiation Safety Officer is sought and who has obtained the attestation and training described in subsections (e) and (f) of this Section; or
- d) Is an authorized user or authorized medical physicist 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 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 approval is sought. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist or authorized user, as appropriate, who is authorized for the types of use for which 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 will be posted on the NRC's website.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

**Section 335.9020 Training for Experienced Radiation Safety Officer (Repealed)**

(Source: Repealed at 27 Ill. Reg. 10057, effective June 30, 2003)

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

Except as provided in Section 335.9160, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.3010 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 and who has obtained the attestation required by subsection (d) 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 material for uptake, dilution and excretion studies as described in subsections (c)(1) and (2) of this Section; and
  - 2) Pass an examination administered by diplomate of the specialty board, that evaluates knowledge and competence in radiation safety, radionuclide handling and quality control; or
- b) Is an authorized user who meets the requirements of Section 335.9040 or 335.9050 or equivalent U.S. Nuclear Regulatory Commission or Agreement 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
- 2) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9040, 335.9050 or 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement 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.
- d) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) or (c) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the uses authorized by Section 335.3010. 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.

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 35 Ill. Reg. 884, effective December 30, 2010)

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

Except as provided in Section 335.9160, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.4010 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 and who has obtained the attestation described in subsection (d) of this Section. 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 material for imaging and localization studies as described in subsection (c) of this Section; and
  - 2) Pass an examination administered by diplomate of the specialty board, that evaluates knowledge and competence in radiation safety, radionuclide handling and quality control; or
- b) Is an authorized user who meets the requirements of Section 335.9050 and subsection (c)(2)(G) of this Section or equivalent U.S. Nuclear Regulatory Commission or Agreement 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 the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include at a minimum:
  - 1) Classroom and laboratory training in the following areas:
    - A) Radiation physics and instrumentation;
    - B) Radiation protection;
    - C) Mathematics pertaining to the use and measurement of radioactivity;
    - D) Chemistry of radioactive material for medical use;
    - E) Radiation biology; and
  - 2) Work experience under the supervision of an authorized user who meets the requirements in this Section, 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, 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;
  - F) Administering dosages of radioactive drugs to patients or human research subjects;
  - G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring, and testing the eluate for radionuclidic purity and processing the eluate with reagent kits to prepare labeled radioactive drugs.
- d) Has obtained written attestation 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. 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 will be posted on the NRC's website.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

**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, a licensee

shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.5010 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 and who has the work experience required by subsection (b)(2)(F) of this Section and has obtained the attestation described in subsection (c) of this Section. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:
  - 1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in subsection (b)(1) through (b)(2)(E) of this Section. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
  - 2) Pass an examination administered by diplomate of the specialty board that evaluates 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 will be posted on the NRC's website.

- 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;
    - 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 requirements. A supervising authorized user who meets the requirements in subsection (b) of this Section shall 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. 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:
    - 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 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; or
  - iv) Parenteral administration of any other radionuclide for which a written directive is required.
- c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (b) of this Section or subsection (a)(1) of this Section together with subsection (b)(2)(F) 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. The 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 requirements. The preceptor authorized user who meets the requirements in subsection (b) of this Section shall 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.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

**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, 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) of this Section and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who has obtained the attestation described in subsection (d) of this Section; or
- b) Is an authorized user who meets the requirements of Section 335.9070 or Section 335.9050 for the uses identified in subsection 335.9050(b)(2)(F)(i) or (ii) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

has: c) Has obtained the attestation described in subsection (d) of this Section and

- 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 of this Section, Section 335.9050, 335.9070, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements of subsection 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(i) or (ii). 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.

- d) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a) 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 Section 335.5010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9070, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in Section 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(i) or (ii).

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 35 Ill. Reg. 884, effective December 30, 2010)

**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, 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) of this Section and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who has obtained the attestation described in subsection (d) 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 will be posted on the NRC's website.

- b) Is an authorized user who meets the requirements of Section 335.9050 for the uses identified in subsection 335.9050(b)(2)(F)(ii), or equivalent U.S. Nuclear Regulatory Commission or Agreement 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
  
- 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 requirements. A supervising authorized user who meets the requirements of Section 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(ii). 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 greater than 1.22 GBq (33 mCi) of sodium iodide I-131.

- d) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a) 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 Section 335.5010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in Section 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(ii).

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

**Section 335.9080 Training for the Parenteral Administration of Unsealed Radioactive 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 Section 335.9050 for a use identified in subsection 335.9050(b)(2)(F)(iii) or (iv) or equivalent U.S. Nuclear Regulatory Commission or Agreement 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 requirements and who meets the requirements in subsection (d) of this 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. Nuclear Regulatory Commission or an Agreement State. The individual shall 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 administration 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 or parenteral

administration of any other radionuclide for which a written directive is required. 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; 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 requirements in the parenteral administration of radioactive material for which a written directive is required. The experience shall include administration of any beta emitter, any photon-emitting radionuclide with a photon energy less than 150 keV 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 have experience in administering dosages as identified in Section 335.9050(b)(2)(F)(iii) or (iv). The work experience shall involve:
- A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation surveys;
  - B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
  - C) Calculating, measuring and safely preparing patient or human research subject dosages;
  - D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
  - E) Using procedures to contain spilled radioactive 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, any photon-emitting radionuclide with a photon energy less than 150 keV or at least 3 cases involving the parenteral administration of any other radionuclide for which a written directive is required.

- e) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (b), (c) or (d) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in Section 335.9050 shall have experience in administering dosages identified in subsections 335.9050(b)(2)(F)(iii) or (iv).

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 35 Ill. Reg. 884, effective December 30, 2010)

**Section 335.9090 Training for Therapeutic Use of Colloidal Chromic Phosphorus-32 Labeled Phosphate Compound or Gold-198 (Repealed)**

(Source: Repealed at 27 Ill. Reg. 10057, effective June 30, 2003)

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

Except as provided in Section 335.9160, the licensee shall require the authorized user of a manual brachytherapy source under the provisions and requirements of Subpart H 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 and who has obtained the attestation described in subsection (c) 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 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 diplomate of the specialty board that evaluates 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 will be posted on the NRC's website.

- 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:

- 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 requirements. The work experience shall include:

- 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 requirements. The experience shall be obtained as 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.
- c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) or (b) of this Section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources 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.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

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

Except as provided in Section 335.9160, 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 or equivalent U.S. Nuclear Regulatory Commission or Agreement 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:

- 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 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.
- c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (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 35 Ill. Reg. 884, effective December 30, 2010)

### **Section 335.9130 Training for Use of Sealed Sources for Diagnosis**

Except as provided in Section 335.9160 of this Part, the licensee shall require the authorized user of a sealed source for diagnostic use in a device authorized in Section 335.6010 of this Part to be a physician, dentist or podiatrist who:

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

- b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:
- 1) Radiation physics and instrumentation;
  - 2) Radiation protection;
  - 3) Mathematics pertaining to the use and measurement of radioactivity;
  - 4) Radiation biology; and
  - 5) Training in the use of the device for the uses requested.

(Source: Amended at 30 Ill. Reg. 9029, effective April 28, 2006)

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

Except as provided in Section 335.9160, the licensee shall require the authorized user of a sealed source under the provisions and requirements of Subpart I 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 and who has obtained the attestation described in subsection (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) 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 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 will be posted on the NRC's website.

- 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:
      - 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 requirements. The work experience shall include:
      - 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 requirements. The experience shall be obtained as 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.
- c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) and (d) or (b) and (d) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the type of therapeutic medical unit for which the individual is requesting authorized user status. The 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 requirements for each type of therapeutic medical unit for which the individual is requesting authorized user status.
- d) Has received training in device operation, safety procedures and clinical use for the type of therapeutic medical unit for which authorization is sought. This training requirement may be met by satisfactory completion of a training program provided 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 35 Ill. Reg. 884, effective December 30, 2010)

### **Section 335.9150 Training for Authorized Medical Physicist**

Except as provided in Section 335.9160, the licensee shall require the authorized medical

physicist 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 has obtained the attestation described in subsection (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 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
    - 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, 335.9140 or 335.9160;
  - 3) Pass an examination administered by diplomate of the specialty board that evaluates 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 will be posted on the NRC's website.

- 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 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 types of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical

radiation facilities that provide high energy, external beam therapy and brachytherapy services and shall include:

- 1) Performing sealed source leak tests and inventories;
  - 2) Performing decay corrections;
  - 3) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units and remote afterloading units as applicable;
  - 4) Conducting radiation monitoring around external beam treatment units, stereotactic radiosurgery units and remote afterloading units, as applicable; and
- c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (a)(1), (a)(2) and (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 for which the individual is requesting authorized medical physicist status. The attestation shall 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 requirements for an authorized medical physicist for each type of use for which the individual is requesting authorized medical physicist status.
- d) Has training in the type 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 or by training supervised by an authorized medical physicist authorized for the type of use for which the individual is seeking authorization.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)

**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 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 October 24, 2007 need not comply with the training requirements of Sections 335.9010 and 335.9150.

- 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, 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 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.
- 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 35 Ill. Reg. 884, effective December 30, 2010)

#### **Section 335.9170 Physician Training in a 3-Month Program (Repealed)**

(Source: Repealed at 27 Ill. Reg. 10057, effective June 30, 2003)

#### **Section 335.9180 Recentness of Training**

The training and experience specified in Subpart J of this Part shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

(Source: Amended at 27 Ill. Reg. 10057, effective June 30, 2003)

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

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

(Source: Amended at 32 Ill. Reg. 9247, effective June 13, 2008)

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

(Source:

Repealed at 32 Ill. Reg. 9247, effective June 13, 2008)