

§ 35.900

10 CFR Ch. I (1–1–05 Edition)

oncology, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sept. 16, 2004]

Subpart I [Reserved]

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

- (a) Is certified by the—
 - (1) American Board of Health Physics in Comprehensive Health Physics;
 - (2) American Board of Radiology;
 - (3) American Board of Nuclear Medicine;
 - (4) American Board of Science in Nuclear Medicine;
 - (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

(b) Has had classroom and laboratory training and experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of by-product material; or

(c) Is an authorized user identified on the licensee's license.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who—

(a) Is certified in—

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows—

(1) 40 hours of classroom and laboratory training that includes—

Nuclear Regulatory Commission

§ 35.920

- (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry; and
- (2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes—
- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
 - (iii) Administering dosages to patients or human research subjects and using syringe radiation shields;
 - (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
 - (v) Patient or human research subject follow up; or
- (c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who—

- (a) Is certified in—
 - (1) Nuclear medicine by the American Board of Nuclear Medicine;
 - (2) Diagnostic radiology by the American Board of Radiology;
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
 - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows—

(1) 200 hours of classroom and laboratory training that includes—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Radiopharmaceutical chemistry; and
- (v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes—

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
- (iii) Calculating and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent the medical event of byproduct material;
- (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes—

- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- (iii) Administering dosages to patients or human research subjects and using syringe radiation shields;