

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;

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(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 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.

§ 35.930 Training for therapeutic use of unsealed byproduct material.

Except as provided in §35.57, the licensee shall require the authorized user of radiopharmaceuticals in §35.300 to be a physician who—

(a) Is certified by—

(1) The American Board of Nuclear Medicine;

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

(4) The American Osteopathic Board of Radiology after 1984; or

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

(1) 80 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; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes—

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

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§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in §35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows—

(a) 80 hours of classroom and laboratory training that includes—

(1) Radiation physics and instrumentation;

(2) Radiation protection,

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

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in §35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows—

(a) 80 hours of classroom and laboratory training that includes—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in §35.57, the licensee shall require the authorized