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(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(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; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

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

(a) Obtained from:
   (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or
   (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or
   (b) Excluding production of PET radionuclides, prepared by:
      (1) An authorized nuclear pharmacist;
      (2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or
      (3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or
      (c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or
      (d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—
   (1) Patient or human research subject control;
   (2) Visitor control, including—
      (i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and
      (ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;
   (3) Contamination control;
   (4) Waste control; 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 retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall—
   (1) Quarter the patient or the human research subject in—
      (i) A private room with a private sanitary facility; or
      (ii) A room, with a private sanitary facility, with another individual who

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in §35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC’s Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(b)(1) 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 byproduct material requiring a written directive. The training and experience must include—

(i) 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 byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in §35.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., §35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must 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;