

## Nuclear Regulatory Commission

## § 35.310

(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;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving—

(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 byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(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 §§ 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sept. 16, 2004; 70 FR 16364, Mar. 30, 2005]

### Subpart E—Unsealed Byproduct Material—Written Directive Required

#### § 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 a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) 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, before October 24, 2005, § 35.920; 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sept. 16, 2004]

#### § 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—