§ 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;

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(c) 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

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

Subpart E—Unsealed Byproduct Material—Written Directive Required

§ 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 sufficient to function independently as an authorized user for the medical uses authorized under §§35.100 and 35.200.

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

(a) 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—

(b) 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under §35.75, a licensee shall—

(b) 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]