Nuclear Regulatory Commission

§ 35.190

Training for uptake, dilution, and excretion studies.

Except as provided in §35.57, the licensee shall require an authorized user of unsealed byproduct material for the

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under §35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies 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, or 35.390 and 35.290(c)(1)(ii)(G); 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 a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
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