§ 35.69  Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70  Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under §35.75.

(c) A licensee shall retain a record of each survey in accordance with §35.2070.

§ 35.75  Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). 1

(b) A licensee shall provide the released individual, or the individual’s parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with §35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with §35.2075(b).


§ 35.80  Provision of mobile medical service.

(a) A licensee providing mobile medical service shall—

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client’s address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client’s address or

1 The current revision of NUREG–1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses” describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).
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§ 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;
   (2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements;
   (3) 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;
   (4) 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;
   (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.192 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it—
   (1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
   (2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with §35.2092.

§ 35.2092 (a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it—
   (1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
   (2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with §35.2092.

§ 35.300 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;
   (2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements;
   (3) 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;
   (4) 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;
   (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.3092 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it—
   (1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
   (2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with §35.2092.

§ 35.400 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;
   (2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements;
   (3) 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;
   (4) 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;
   (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.500 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;
   (2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements;
   (3) 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;
   (4) 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;
   (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.600 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;
   (2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements;
   (3) 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;
   (4) 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;
   (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.700 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;
   (2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements;
   (3) 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;
   (4) 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;
   (5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.