

## Nuclear Regulatory Commission

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plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

### § 35.75 Release of individuals containing radiopharmaceuticals or permanent implants.

(a) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).<sup>1</sup>

(b) The licensee shall provide the released individual 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 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

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

(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered,

<sup>1</sup>Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem).

(2) Using an occupancy factor less than 0.25 at 1 meter,

(3) Using the biological or effective half-life, or

(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

[62 FR 4133, Jan. 29, 1997]

### § 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the

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survey, and the initials of the individual who performed the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

### § 35.90 Storage of volatiles and gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

### § 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.2001 of this chapter if it:

(1) Holds byproduct material for decay a minimum of ten half-lives;

(2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for three years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

## 10 CFR Ch. I (1-1-01 Edition)

### Subpart D—Uptake, Dilution, and Excretion

#### § 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

[59 FR 61784, Dec. 2, 1994]

#### § 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

### Subpart E—Imaging and Localization

#### § 35.200 Use of unsealed byproduct material for imaging and localization studies.

A licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

[59 FR 61784, Dec. 2, 1994]