

§ 35.410

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§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant therapy. To satisfy this requirement, the instruction must describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient or human research subject control;
- (4) Procedures for visitor control; and
- (5) Procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61785, Dec. 2, 1994]

§ 35.415 Safety precautions.

(a) For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to § 35.75 of this part, a licensee shall:

- (1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy.
- (2) Post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;
- (3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and
- (4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for three years a record of each survey

that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61785, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994; 62 FR 4133, Jan. 29, 1997]

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy 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, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart H—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and
- (b) Iodine-125 as a sealed source in a portable imaging device.

§ 35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per