

§ 35.415

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the—

- (1) Size and appearance of the brachytherapy sources;
 - (2) Safe handling and shielding instructions;
 - (3) Patient or human research subject control;
 - (4) Visitor control, including both:
 - (i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and
 - (ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and
 - (5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.
- (b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

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

- (1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;
- (2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and
- (3) 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.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source—

- (1) Dislodged from the patient; and
 - (2) Lodged within the patient following removal of the source applicators.
- (c) A licensee shall notify the Radiation Safety Officer, or his or her des-

10 CFR Ch. I (1–1–11 Edition)

ignee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

- (1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);
- (2) Determined source positioning accuracy within applicators; and
- (3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

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

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published