

§ 35.415

10 CFR Ch. I (1–1–12 Edition)

(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-

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