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- (v) Radiation biology; and
- (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§35.390 or 35.396, or, before October 24, 2005, §35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in §§35.390 or 35.930 must have experience in administering dosages as specified in §§35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve—
 - (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
 - (v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive.

The written attestation must be signed by a preceptor authorized user who meets the requirements in §§35.390, 35.396, or, before October 24, 2005, §35.930, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in §35.390, or, before October 24, 2005, §35.930, must have experience in administering dosages as specified in §§35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).

[70 FR 16365, Mar. 30, 2005]

Subpart F—Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

- (a) As approved in the Sealed Source and Device Registry; or
- (b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of §35.49(a) are met.

§ 35.404 Surveys after source implant and removal.

- (a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.
- (b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.
- (c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with §35.2404.

§ 35.406 Brachytherapy sources accountability.

- (a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.
- (b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return

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brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(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 designee, 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.