

§ 35.310 Safety instruction.

(a) * * *

(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.

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■ 10. In § 35.315, paragraph (b) is revised to read as follows:

§ 35.315 Safety precautions.

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(b) 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.

■ 11. In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

(b) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), or, before October 24, 2004, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2004, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve—

* * * * *

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), or, before October 24, 2004, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2004, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

■ 12. In § 35.392, paragraph (b), the introductory text of paragraph (c)(2), and

paragraph (c)(3) are revised to read as follows:

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

* * * * *

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements; or

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve—

* * * * *

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

■ 13. In § 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

* * * * *

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements; or

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a),

35.390(b), 35.394, or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve—

* * * * *

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

■ 14. In § 35.432, paragraph (b) is revised to read as follows:

§ 35.432 Calibration measurements of brachytherapy sources.

* * * * *

(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.

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■ 15. In § 35.490, the introductory text of paragraph (b)(1)(ii), paragraphs (b)(2) and (b)(3) are revised to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(b) * * *

(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements at a medical institution, involving—

* * * * *

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or