

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

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(b) Prepared by:

(1) An authorized nuclear pharmacist;
(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

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5. In § 35.190, paragraph (b), the introductory text of paragraph (c)(1)(ii), and paragraph (c)(2) are revised to read as follows:

§ 35.190 Training for uptake, dilution, and excretion studies.

* * * * *

(b) Is an authorized user under §§ 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements; or

* * * * *

(c) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, involving—

* * * * *

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(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 § 35.100.

6. In § 35.200, paragraph (b) is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

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(b) Prepared by:

(1) An authorized nuclear pharmacist;
(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

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7. In § 35.290, paragraph (b), the introductory text of paragraph (c)(1)(ii), and paragraph (c)(2) are revised to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(b) Is an authorized user under § 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements; or

(c) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements, involving —

* * * * *

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(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 §§ 35.100 and 35.200.

8. In § 35.300, paragraph (b) is revised to read as follows:

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

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(b) Prepared by:

(1) An authorized nuclear pharmacist;
(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

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9. In § 35.310, paragraph (a)(5) is revised to read as follows:

§ 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.

* * * * *

(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: