

§ 35.11

requirements contained in §§ 35.32 and 35.33.

[51 FR 36951, Oct. 16, 1986, as amended at 57 FR 41378, Sept. 10, 1992; 59 FR 61782, Dec. 2, 1994; 62 FR 52186, Oct. 6, 1997]

§ 35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.25, unless prohibited by license condition.

(c) An individual may prepare unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.25, unless prohibited by license condition.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61782, Dec. 2, 1994]

§ 35.12 Application for license, amendment, or renewal.

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instruc-

10 CFR Ch. I (1-1-01 Edition)

tions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to § 30.6 of this chapter.

(e) An applicant that satisfies the requirements specified in 10 CFR 33.13 may apply for a Type A specific license of broad scope.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61782, Dec. 2, 1994]

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before it receives or uses byproduct material for a clinical procedure permitted under this part but not permitted by the license issued pursuant to this part;

(b) Before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

(1) An authorized user certified by the organizations specified in paragraph (a) of § 35.910, § 35.920, § 35.930, § 35.940, § 35.950, or § 35.960;

(2) An authorized nuclear pharmacist certified by the organization specified in paragraph (a) of § 35.980;

(3) Identified as an authorized user or an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or

(4) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(e) Before it adds to or changes the areas of use or address or addresses of

Nuclear Regulatory Commission

§ 35.20

use identified in the application or on the license.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61782, Dec. 2, 1994]

§ 35.14 Notifications.

(a) A licensee shall provide to the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to § 35.13 (b)(1) through (b)(4).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

[59 FR 61782, Dec. 2, 1994]

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(a) The provisions of § 35.13(b);

(b) The provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(c) The provisions of § 35.14(a); and

(d) The provisions of § 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.

[59 FR 61782, Dec. 2, 1994]

§ 35.18 License issuance.

The Commission shall issue a license for the medical use of byproduct material if:

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;

(b) The applicant has paid any applicable fee as provided in part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of part 30 of this chapter.

[51 FR 36951, Oct. 16, 1986, as amended at 63 FR 31607, June 10, 1998]

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements

§ 35.20 ALARA program.

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education