

Nuclear Regulatory Commission

§ 35.8

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 34120, July 25, 1991; 59 FR 61781, Dec. 2, 1994; 60 FR 48626, Sept. 20, 1995]

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19247, May 27, 1988]

§ 35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities

by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

[59 FR 61781, Dec. 2, 1994]

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

[59 FR 61782, Dec. 2, 1994]

§ 35.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.20, 35.21, 35.22, 35.23, 35.29, 35.31, 35.50, 35.51, 35.52, 35.53, 35.59, 35.60, 35.61, 35.70, 35.75, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, 35.647, 35.980, and 35.981.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, NRC Form NRC 313 is approved under control number 3150-0120.

(2) [Reserved]

(d) OMB has assigned control number 3150-0171 for the information collection

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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-

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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