

Nuclear Regulatory Commission

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(vi) ALARA program reviews described in § 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2)(i) Review, on the basis of safety and with regard to the training and experience standards in subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or

(ii) Review, pursuant to § 35.13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under § 35.31 of this part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

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

§ 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organiza-

tional freedom, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(c), shall:

(1) Instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of byproduct material;

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(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

(c) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

[51 FR 36951, Oct. 16, 1991, as amended at 56 FR 34121, July 25, 1991; 59 FR 61782, Dec. 2, 1994]

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with subparts D, E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for li-

cence, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive¹ is prepared for:

¹If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is