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Subpart B—General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing—

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to—

(1) Identify radiation safety problems;

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

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if—

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 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)(1), shall—

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(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(b)(2), shall—

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information—

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, 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 is acceptable. The