§ 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.

§ 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.

(b) 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.
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.

(d) The licensee shall retain a copy of the written directive in accordance with §35.2040.

§35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient’s or human research subject’s identity is verified before each administration; and
2. Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee’s use of byproduct material—

1. Verifying the identity of the patient or human research subject;
2. Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
3. Checking both manual and computer-generated dose calculations; and
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§35.600 or 35.1000.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with §35.2041.

§35.49 Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use—

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;
(b) Sealed sources or devices non-commercially transferred from a Part