

pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in §35.55(a) of this chapter with the written attestation signed by a preceptor as required by §35.55(b)(2) of this chapter; or

(ii) The Commission or Agreement State license, or

(iii) Commission master materials licensee permit, or

(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

[59 FR 61780, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994, as amended at 60 FR 324, Jan. 4, 1995; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 67 FR 77652, Dec. 19, 2002; 71 FR 15007, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 72 FR 55929, Oct. 1, 2007]

**§32.74 Manufacture and distribution of sources or devices containing by-product material for medical use.**

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if:

(1) The applicant satisfies the general requirements in §30.33 of this chapter;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The byproduct material contained, its chemical and physical form, and amount;

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(iv) For devices containing byproduct material, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content;

(viii) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device;

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*Provided*, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(4) The source or device has been registered in the Sealed Source and Device Registry.

(b)(1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval for test of leakage of radioactive material, the Commission will consider information that includes, but is not limited to:

- (i) Primary containment (source capsule);
- (ii) Protection of primary containment;
- (iii) Method of sealing containment;
- (iv) Containment construction materials;
- (v) Form of contained radioactive material;
- (vi) Maximum temperature withstood during prototype tests;
- (vii) Maximum pressure withstood during prototype tests;
- (viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material;

(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies the applicant otherwise.

[39 FR 26149, July 17, 1974, as amended at 51 FR 36967, Oct. 16, 1986; 62 FR 59276, Nov. 3, 1997; 67 FR 20370, Apr. 24, 2002; 71 FR 15008, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 77 FR 43695, July 25, 2012]

### § 32.201 Serialization of nationally tracked sources.

Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[71 FR 65709, Nov. 8, 2006]

## Subpart D—Sealed Source and Device Registration

### § 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Federal and State Materials and Environmental Management Programs, ATTN: SDDR by an appropriate method listed in § 30.6(a) of this chapter.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient