

4731.3400 SPECIFIC LICENSE; SOURCES OR DEVICES FOR MEDICAL USE; MANUFACTURE AND DISTRIBUTION.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed according to parts 4731.4400 to 4731.4527 for use as a calibration, transmission, or reference source or for the uses listed under parts 4731.4404, 4731.4450, 4731.4460, and 4731.4463 shall be approved if:

- A. the applicant satisfies the general requirements of part 4731.3070;
 - B. the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (1) the radioactive material contained, its chemical and physical form, and amount;
 - (2) details of design and construction of the source or device;
 - (3) 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;
 - (4) for devices containing radioactive material, the radiation profile of a prototype device;
 - (5) details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests;
 - (6) procedures and standards for calibrating sources and devices;
 - (7) legend and methods for labeling sources and devices as to their radioactive content; and
 - (8) instructions for handling and storing the source or device from the radiation safety standpoint. These instructions must be:
 - (a) included on a durable label attached to the source or device;
 - (b) attached to a permanent storage container for the source of device;
- or
- (c) summarized on the label, for instructions that are too lengthy for the label, and printed in detail on a brochure that is referenced on the label;
- C. the label affixed to the source or device, or to the permanent storage container for the source or device, contains:
 - (1) information on the radionuclide;
 - (2) the quantity;

(3) the date of assay; and

(4) a statement that the commissioner has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified under parts 4731.4423, 4731.4450, 4731.4460, and 4731.4463, as appropriate, and to persons who hold equivalent licenses issued by the NRC or an agreement state; and

D. the source or device has been registered in the Sealed Source and Device Registry.

Subp. 2. Alternative testing intervals.

A. 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, the applicant must include in the application sufficient information to demonstrate that the longer interval is justified by:

(1) performance characteristics of the source or device or similar sources or devices; and

(2) design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

B. In determining the acceptable interval for testing leakage of radioactive material, the commissioner shall consider information that includes, but is not limited to:

(1) primary containment (source capsule);

(2) protection of primary containment;

(3) method of sealing containment;

(4) containment construction materials;

(5) form of contained radioactive materials;

(6) maximum temperature withstood during prototype tests;

(7) maximum pressure withstood during prototype tests;

(8) maximum quantity of contained radioactive material;

(9) radiotoxicity of contained radioactive material; and

(10) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

Subp. 3. Application pending. If an application was filed according to subpart 1 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 until the commissioner issues the license or notifies the applicant otherwise.

Statutory Authority: *MS s 144.1201; 144.1202; 144.1203; 144.1204; 144.1205*

History: *29 SR 755; 32 SR 831; 33 SR 1440; 40 SR 145*

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