

WAC 246-235-102 Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under chapter 246-240 WAC for use as a calibration, transmission, or reference source or for the uses listed in WAC 246-240-251, 246-240-301, and 246-240-351 will be approved if:

(1) The applicant satisfies the general requirements in WAC 246-235-020;

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

(a) The radioactive material contained, its chemical and physical form and amount;

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

(c) 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;

(d) For devices containing radioactive material, the radiation profile of a prototype device;

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

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

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

(h) 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: Provided that instructions which are too lengthy for the 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 named source or device is licensed by the department for distribution to persons licensed under chapter 246-240 WAC or under equivalent regulations of the NRC or an agreement state: Provided that the labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(4) The source or device has been registered in the sealed source and device registry.

(5) If the applicant desires that the source or device be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the 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.

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

(a) Primary containment (source capsule);

(b) Protection of primary containment;

(c) Method of sealing containment;

- (d) Containment construction materials;
- (e) Form of contained radioactive material;
- (f) Maximum temperature withstood during prototype tests;
- (g) Maximum pressure withstood during prototype tests;
- (h) Maximum quantity of contained radioactive material;
- (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-235-102, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-235-102, filed 11/22/13, effective 12/23/13; WSR 07-14-131, § 246-235-102, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-235-102, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-235-102, filed 6/8/98, effective 7/9/98.]