

3701:1-46-44**Manufacture and distribution of sources or devices containing radioactive material for medical use.**

- (A) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Chapter 3701:1-58 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or agreement state for use as a calibration, transmission, or reference source or for the uses listed in rules 3701:1-58-43, 3701:1-58-53, 3701:1-58-55, and 3701:1-58-72 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or agreement state will be approved if:
- (1) The applicant satisfies the general requirements in rule 3701:1-40-15 of the Administrative Code;
 - (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;
 - (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 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 director has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in rules 3701:1-58-26, 3701:1-58-43, 3701:1-58-53, and 3701:1-58-55 of the Administrative Code, as appropriate, and to persons who hold an equivalent license issued by the United States nuclear regulatory commission or an agreement state; and

- (4) The source or device has been registered in the sealed source and device registry.
- (B) The following is applicable:
- (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/she shall include in his/her 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 director 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;
 - (j) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

Effective: 11/08/2015

R.C. 119.032 review dates: 08/24/2015 and 11/01/2020

CERTIFIED ELECTRONICALLY

Certification

10/29/2015

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 10/20/2002, 8/15/05, 1/20/08, 12/22/08