

3701:1-46-30 Radioactive material contained in devices for use under rule 3701:1-46-05 of the Administrative Code; requirements for license to manufacture, or initially transfer.

- (A) An application for a specific license to manufacture, or initially transfer devices containing radioactive material to persons generally licensed under rule 3701:1-46-05 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:
- (1) The applicant satisfies the general requirements of rule 3701:1-40-15 of the Administrative Code;
 - (2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - (a) The device can be safely operated by persons not having training in radiological protection;
 - (b) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of ten per cent of the annual limits specified in paragraph (A) of rule 3701:1-38-12 of the Administrative Code; and
 - (c) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the appendix to this rule.
 - (3) Each device bears a durable, legible, clearly visible label or labels approved by the director which contain in a clearly identified and separate statement:
 - (a) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);
 - (b) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by radionuclide, quantity of radioactivity, and date of determination of the quantity; and
 - (c) The information called for in the following statement in the same or substantially similar form. The receipt, possession, use, and transfer of this device model, serial no., are subject to a general license or the equivalent and the regulations of the United States nuclear regulatory commission or a state with which the United States nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

"CAUTION-RADIOACTIVE MATERIAL"

(Name of manufacturer, or initial transferor)

Devices licensed by the United States nuclear regulatory commission prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

- (4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radionuclide and quantity, the words, "Caution: Radioactive Material," the radiation symbol described in paragraph (A) of rule 3701:1-38-18 of the Administrative Code, and the name of the manufacturer or initial distributor.
 - (5) Each device meeting the criteria of paragraph (C)(13)(a) of rule 3701:1-46-05 of the Administrative Code, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution: Radioactive Material," and, if practicable, the radiation symbol described in paragraph (A) of rule 3701:1-38-18 of the Administrative Code.
- (B) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the director will consider information which 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 material;
 - (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 devices or similarly designed and

constructed devices.

- (C) In the event the applicant desires that the general licensee under rule 3701:1-46-05 of the Administrative Code, or under equivalent regulations of the United States nuclear regulatory commission or an agreement state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten per cent of the annual limits specified in paragraph (A) of rule 3701:1-38-12 of the Administrative Code.

Effective: 12/01/2012

R.C. 119.032 review dates: 09/10/2012 and 09/15/2017

CERTIFIED ELECTRONICALLY

Certification

11/15/2012

Date

Promulgated Under: 119.03
 Statutory Authority: 3748.04
 Rule Amplifies: 3748.04
 Prior Effective Dates: 10/20/2002, 1/20/08, 4/5/09