

3701:1-46-05 Certain measuring, gauging or controlling devices.

- (A) A general license is hereby issued to commercial and industrial firms; research, educational, and medical institutions; individuals in the conduct of their business; and state or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (B) to (D) of this rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
- (B)
- (1) The general license in paragraph (A) of this rule applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:
 - (a) A specific license issued under rule 3701:1-46-30 of the Administrative Code;
 - (b) An equivalent specific license issued by an agreement state; or
 - (c) An equivalent specific license issued by the United States nuclear regulatory commission.
 - (2) The devices must have been received from one of the specific licensees described in paragraph (B)(1) of this rule or through a transfer made under paragraph (C)(9) of this rule.
- (C) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in paragraph (A) of this rule:
- (1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;
 - (2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:
 - (a) Devices containing only krypton need not be tested for leakage of radioactive material, and
 - (b) Devices containing only tritium or not more than 3.7 megabecquerels (one hundred microcuries) of other beta and/or gamma emitting material or three hundred seventy kilobecquerels (ten microcuries) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
 - (3) Shall assure that the tests required by paragraph (C)(2) of this rule and other testing, installation, servicing, and removal from installation involving the

radioactive materials, its shielding or containment, are performed:

- (a) In accordance with the instructions provided by the labels; or
 - (b) By a person holding a specific license pursuant to this chapter and Chapter 3701:1-40 of the Administrative Code or from an agreement state or the United States nuclear regulatory commission to perform such activities;
- (4) Shall maintain records showing compliance with the requirements of paragraphs (C)(2) and (C)(3) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:
- (a) Each record of a test for leakage or radioactive material required by paragraph (C)(2) of this rule must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.
 - (b) Each record of a test of the on-off mechanism and indicator required by paragraph (C)(2) of this rule must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.
 - (c) Each record that is required by paragraph (C)(3) of this rule must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.
- (5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of one hundred eighty-five becquerels (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under Chapters 3701:1-40 and 3701:1-46 of the Administrative Code or by an agreement state or the United States nuclear regulatory commission. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the director. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of one hundred eighty-five becquerels (0.005 microcurie) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the director within thirty days.
- (6) Shall not abandon the device containing radioactive material;
 - (7) Shall not export the device containing radioactive material except in accordance with applicable United States nuclear regulatory commission regulations;
 - (8)

- (a) Shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph (C)(7) of this rule, by transfer to another general licensee as authorized in paragraph (C)(9) of this rule, or to a person authorized to receive the device by a specific license issued under this chapter and Chapter 3701:1-40 of the Administrative Code, utilizing a licensed broker or other authorized waste collector, or equivalent regulations of an agreement state, United States nuclear regulatory commission, or as approved under paragraph (C)(8)(c) of this rule.
- (b) Shall within thirty days after the transfer of a device to a specific licensee or export, furnish a report to the director by an appropriate method listed in rule 3701:1-40-04 of the Administrative Code, The report must contain:
 - (i) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;
 - (ii) The name, address, and license number of the person receiving the device; and
 - (iii) The date of the transfer.
- (c) Shall obtain written director approval before transferring the device to any other specific licensee not specifically identified in paragraph (C)(8)(a) of this rule; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:
 - (i) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;
 - (ii) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (C)(1) of this rule) so that the device is labeled in compliance with rule 3701:1-38-18 of the Administrative Code; however the manufacturer, model number, and serial number must be retained;
 - (iii) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and
 - (iv) Reports the transfer under paragraph (C)(8)(b) of this rule.
- (9) Shall transfer the device to another general licensee only if:
 - (a) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this rule and any safety documents identified in the label of the device. Within thirty days of the transfer, the transferor shall report to the director:
 - (i) The manufacturer's (or initial transferor's) name;
 - (ii) The model number and the serial number of the device transferred;
 - (iii) The transferee's name and mailing address for the location of use; and

- (iv) The name, title, and phone number of the responsible individual identified by the transferee in accordance with paragraph (C)(12) of this rule to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or
 - (b) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.
- (10) Shall comply with the provisions of paragraphs (A) and (B) of rule 3701:1-38-21 of the Administrative Code for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Chapter 3701:1-38 of the Administrative Code.
- (11) Shall respond to written requests from the director to provide information relating to the general license within thirty calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the director, by an appropriate method listed in rule 3701:1-40-04 of the Administrative Code, a written justification for the request.
- (12) Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of responsibility in this regard.
- (13)
 - (a) Shall report, in accordance with paragraphs (C)(13)(b) and (C)(13)(c) of this rule, devices containing at least three hundred seventy megabecquerels (ten millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, thirty-seven megabecquerels (one millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium, or thirty-seven megabecquerels (one millicurie) of americium-241 or any other transuranic, i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (C)(13)(c)(iv) of this rule, represents a separate general license and requires a separate registration and fee.
 - (b) If in possession of a device meeting the criteria of paragraph (C)(13)(a) of this rule, shall report these devices annually to the director and shall pay the fee required by paragraph (S) of rule 3701:1-38-02 of the Administrative Code. Reporting must be done by verifying, correcting, and/or adding to the information provided in a request received from the director. The information must be submitted to the director within thirty days of the date of the request for information or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (C)(13)(a) of this rule is subject to the bankruptcy notification requirement in Chapter 3701:1-40 of the Administrative Code.
 - (c) In reporting the devices, the general licensee shall furnish the following

information and any other information specifically requested by the director:

- (i) Name and mailing address of the general licensee;
 - (ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label);
 - (iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (C)(12) of this rule;
 - (iv) Address or location at which the device(s) are used and/or stored;
 - (v) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and
 - (vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
- (14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the director within thirty days of the effective date of the change.
- (15) May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (C)(2) of this rule need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.
- (D) The director may order the inspection of any facility licensed under this rule if the director determines that an appropriate reason for the inspection exists. These inspections shall be considered as full cost inspections as defined in rule 3701:1-38-02 of the Administrative Code. The reasons the director may conduct for cause inspections include, but are not limited to;
- (1) Failure to respond to official correspondence;
 - (2) Release of radioactive material to the environment;
 - (3) Investigations of alleged violations of department rules; or
 - (4) Failure to comply with the license application process.
- (E) The general license in paragraph (A) of this rule does not authorize the manufacture or import of devices containing radioactive material.

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, 10/4/10