

3701:1-46-02 Purpose and scope.

- (A) This chapter establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. Specific provisions of Chapter 3701:1-40 of the Administrative Code are applicable to general licenses established by this chapter. These provisions are specified in rule 3701:1-46-03 of the Administrative Code or in the particular general license.
- (B) This chapter prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to persons generally licensed under Chapter 3701:1-46 or 3701:1-58 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state .
- (C) This chapter also prescribes certain rules governing holders of these licenses. In addition, this chapter prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of the licensee or person and rules governing holders of such licenses. Further, this chapter describes procedures and prescribes requirements for the issuance of sealed source and device certificates (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources which are to be used by persons specifically licensed under Chapter 3701:1-40 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state.
- (D) The provisions and requirements of this chapter are in addition to, and not in substitution for, other requirements of Chapter 3701:1-40 of the Administrative Code which apply to applications and licenses subject to this chapter.

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, 10/4/10

3701:1-46-31 Radioactive material contained in devices for use under rule 3701:1-46-05 of the Administrative Code: conditions of licenses.

- (A) If a device containing radioactive material is to be transferred for use under the general license contained in rule 3701:1-46-05 of the Administrative Code, each person that is licensed under rule 3701:1-46-30 of the Administrative Code shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes:
- (1) A copy of rule 3701:1-46-05 of the Administrative Code; if paragraphs (C)(2) to (C)(4), or (C)(13) of rule 3701:1-46-05 of the Administrative Code do not apply to the particular device, those paragraphs may be omitted;
 - (2) A copy of rule 3701:1-46-03, paragraphs (A) and (B) of rule 3701:1-38-21, and rule 3701:1-40-21 of the Administrative Code;
 - (3) A list of the services that can only be performed by a specific licensee;
 - (4) Information on acceptable disposal options including estimated costs of disposal at the time of the purchase;
 - (5) A copy of rule 3701:1-38-05 of the Administrative Code which provides for penalties for improper disposal; and
 - (6) The device has been registered in the sealed source and device registry.
- (B) If radioactive material is to be transferred in a device for use under an equivalent general license of the United States nuclear regulatory commission or an agreement state, each person that is licensed under rule 3701:1-46-30 of the Administrative Code shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:
- (1) A copy of paragraphs (A) and (B) of rule 3701:1-38-21, and rules 3701:1-40-21, 3701:1-46-03, and 3701:1-46-05 of the Administrative Code;
 - (2) A list of the services that can only be performed by a specific licensee;
 - (3) Information on acceptable disposal options including estimated costs of disposal at the time of the purchase; and
 - (4) The name, address, and phone number of the contact at the United States nuclear regulatory commission or the agreement state regulatory agency from which additional information may be obtained.
- (C) An alternate approach to informing customers may be proposed by the licensee for approval by the director.

(D) If a notification of bankruptcy has been made under paragraph (F) of rule 3701:1-40-16 of the Administrative Code, or the license is to be terminated, each person licensed under rule 3701:1-46-30 of the Administrative Code shall provide, upon request, to the director, and if appropriate, to the United States nuclear regulatory commission and any appropriate agreement state records of final disposition required under paragraph (C) of rule 3701:1-46-32 of the Administrative Code.

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, 1/20/08, 12/1/12

3701:1-46-33 Luminous safety devices for use in aircraft: requirements for license to manufacture, assemble, repair or initially transfer.

An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under rule 3701:1-46-07 of the Administrative Code, will be approved if:

- (A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;
- (B) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:
 - (1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;
 - (2) Details of construction and design;
 - (3) Details of the method of binding or containing the tritium or promethium-147;
 - (4) Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;
 - (5) Quality assurance procedures to be followed that are sufficient to ensure compliance with rule 3701:1-46-35 of the Administrative Code; and
 - (6) Any additional information, including experimental studies and tests, required by the director to facilitate a determination of the safety of the device.
- (C) Each device will contain no more than three hundred seventy gigabecquerels (ten curies) of tritium or 11.1 gigabecquerels (three hundred millicuries) of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed five microgray (0.5 millirad) per hour at ten centimeters from any surface when measured through fifty milligrams per square centimeter of absorber.
- (D) The director determines that:
 - (1) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;
 - (2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;
 - (3) The device is so designed that it cannot easily be disassembled; and
 - (4) Prototypes of the device have been subjected to and have satisfactorily passed the tests prescribed in paragraph (E) of this rule.

(E) The applicant shall subject at least five prototypes of the device to tests as follows:

- (1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.
- (2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (E)(3) of this rule.
- (3) Device designs are rejected for which the following has been detected for any unit:
 - (a) A leak resulting in a loss of 0.1 per cent or more of the original amount of tritium or promethium-147 from the device; or
 - (b) Surface contamination of tritium or promethium-147 on the device of more than two thousand two hundred disintegrations per minute per one hundred square centimeters of surface area; or
 - (c) Any other evidence of physical damage.

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

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, 1/20/08

3701:1-46-35 Luminous safety devices for use in aircraft: quality assurance; prohibition of transfer.

- (A) Each person licensed under rule 3701:1-46-33 of the Administrative Code shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.
- (B) Each person licensed under rule 3701:1-46-33 of the Administrative Code shall:
 - (1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components if the distributed devices are capable of performing their intended functions; and
 - (2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (C) of this rule and in a license issued under rule 3701:1-46-33 of the Administrative Code, to provide at least ninety five per cent confidence that the lot tolerance per cent defective of five per cent will not be exceeded.
- (C) The licensee shall subject each inspection lot to:
 - (1) Tests that adequately take into account the individual, aggregate, and cumulative effects of the environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.
 - (2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:
 - (a) A leak test resulting in a loss of 0.1 per cent or more of the original amount of tritium or promethium-147 from the device;
 - (b) Levels of radiation in excess of five microgray (0.5 millirad) per hour at ten centimeters from any surface when measured through fifty milligrams per square centimeter of absorber, if the device contains promethium-147; and
 - (c) Any other criteria specified in the license issued under rule 3701:1-46-33 of the Administrative Code.
- (D) No person licensed under rule 3701:1-46-33 of the Administrative Code shall transfer to persons generally licensed under rule 3701:1-46-07 of the Administrative Code, or under an equivalent general license from an agreement state or the United States nuclear regulatory commission:
 - (1) Any luminous safety device tested and found defective under any condition of a license issued under rule 3701:1-46-33 of the Administrative Code, or paragraph (B) of this rule, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or
 - (2) Any luminous safety device contained within any lot that has been sampled and

rejected as a result of the procedures in paragraph (B)(2) of this rule, unless:

- (a) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under rule 3701:1-46-33 of the Administrative Code; and
- (b) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (B)(2) and (D)(2)(a) of this rule and any other criteria that may be required as a condition of the license issued under rule 3701:1-46-33 of the Administrative Code.

Replaces: 3701:1-46-35

Effective: 11/08/2015

R.C. 119.032 review dates: 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, 1/20/08, 12/1/12

3701:1-46-36 Luminous safety devices for use in aircraft: material transfer reports.

- (A) Each person licensed under rule 3701:1-46-33 of the Administrative Code shall file an annual report with the director at the following address:

"Ohio Department of Health
Bureau of Environmental Health and Radiation Protection
246 North High Street
Columbus, Ohio 43215"

which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under rule 3701:1-46-07 of the Administrative Code. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty days thereafter. If no transfers have been made to persons generally licensed under rule 3701:1-46-07 of the Administrative Code during the reporting period, the report must so indicate.

- (B) Each person licensed under rule 3701:1-46-33 of the Administrative Code shall report annually all transfers of devices to persons for use under a general license in an agreement state or nuclear regulatory commission's regulations that are equivalent to rule 3701:1-46-33 of the Administrative Code to the responsible agreement state or United States nuclear regulatory commission. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular agreement state or the United States nuclear regulatory commission during the reporting period, this information must be reported to the responsible agreement state agency or to the United States nuclear regulatory commission upon request of the agency.

Replaces: 3701:1-46-36

Effective: 11/08/2015

R.C. 119.032 review dates: 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, 1/20/08, 12/1/12

3701:1-46-37 Calibration or reference sources containing americium-241 or radium-226: requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under rule 3701:1-46-08 of the Administrative Code, will be approved if:

- (A) The applicant satisfies the general requirements of rule 3701:1-40-15 of the Administrative Code;
- (B) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
 - (1) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;
 - (2) Details of construction and design;
 - (3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
 - (4) Procedures for and results of prototype testing of sources, which are designed to contain more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;
 - (5) Details of quality control procedures to be followed in manufacture of the source;
 - (6) Description of labeling to be affixed to the source or the storage container for the source;
 - (7) Any additional information, including experimental studies and tests, required by the director to facilitate a determination of the safety of the source.
- (C) Each source will contain no more than one hundred eighty-five kilobecquerels (five microcuries) of americium-241 or radium-226.
- (D) The director determines, with respect to any type of source containing more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241, or radium-226 that:
 - (1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and
 - (2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed in paragraph (E) of this rule.

- (E) The applicant shall subject at least five prototypes of each source that is designed to contain more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226 to tests as follows:
- (1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.
 - (2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.
 - (3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (E)(4) of this rule.
 - (4) Source designs are rejected for which the following has been detected for any unit: removal of more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

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, 1/20/08, 10/4/10

3701:1-46-39 Calibration or reference sources containing americium-241 or radium-226: leak testing of each source.

Each person licensed under rule 3701:1-46-37 of the Administrative Code shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 prior to transferring the source to a general licensee under rule 3701:1-46-08 of the Administrative Code. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than one hundred eighty-five becquerels (0.005 microcurie) of americium-241 or radium-226 by the methods described in this rule, the source shall not be transferred to a general licensee under rule 3701:1-46-08 of the Administrative Code, or under an equivalent general license from an agreement state or the United States nuclear regulatory commission.

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, 1/20/08, 12/1/12

3701:1-46-40 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under rule 3701:1-46-10 of the Administrative Code will be approved if:

- (A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;
- (B) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:
 - (1) Chemical and physical form and maximum quantity of strontium-90 in the device;
 - (2) Details of construction and design of the source of radiation and its shielding;
 - (3) Radiation profile of a prototype device;
 - (4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;
 - (5) Details of quality control procedures to be followed in manufacture of the device;
 - (6) Description of labeling to be affixed to the device;
 - (7) Instructions for handling and installation of the device;
 - (8) Any additional information, including experimental studies and tests, required by the director to facilitate a determination of the safety of the device;
- (C) Each device will contain no more than 1.85 megabecquerels (fifty microcuries) of strontium-90 in an insoluble form;
- (D) Each device will bear durable, legible labeling which includes the radiation symbol prescribed by paragraph (A) of rule 3701:1-38-18 of the Administrative Code, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;
- (E) The director determines that:
 - (1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

- (2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of five millisieverts (0.5 rem) in a year under ordinary circumstances of use;
 - (3) The device is so designed that it cannot be easily disassembled;
 - (4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (F) of this rule.
 - (5) Quality control procedures have been established to satisfy the requirements of rule 3701: 1-46-41 of the Administrative Code.
- (F) The applicant shall subject at least five prototypes of the device to tests as follows:
- (1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.
 - (2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (F)(3) of this rule.
 - (3) Device designs are rejected for which the following has been detected for any unit:
 - (a) A leak resulting in a loss of 0.1 per cent or more of the original amount of strontium-90 from the device;
 - (b) Surface contamination of strontium-90 on the device of more than two thousand two hundred disintegrations per minute per one hundred square centimeters of surface area; or
 - (c) Any other evidence of physical damage.
- (G) The device has been registered in the sealed source and device registry.

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, 1/20/08

3701:1-46-41 Ice detection devices containing strontium-90: quality assurance; prohibition of transfer.

- (A) Each person licensed under rule 3701:1-46-40 of the Administrative Code shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.
- (B) Each person licensed under rule 3701:1-46-40 of the Administrative Code shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least one hundred square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than one hundred square centimeters. The detection on the filter paper of more than two thousand two hundred disintegrations per minute of radioactive material per one hundred square centimeters of surface wiped shall be cause for rejection of the tested device.
- (C) Each person licensed under rule 3701:1-46-40 of the Administrative Code shall :
 - (1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and
 - (2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (D) of this rule and in a license issued under the rule 3701:1-46-40 of the Administrative Code, to provide at least ninety five per cent confidence that the lot tolerance per cent defective of five per cent will not be exceeded.
- (D) Each person licensed under rule 3701:1-46-40 of the Administrative Code shall subject each inspection lot to:
 - (1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.
 - (2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 per cent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under rule 3701:1-46-40 of the Administrative Code.
- (E) No person licensed under rule 3701:1-46-40 of the Administrative Code shall transfer to persons generally licensed under rule 3701:1-46-10 of the Administrative Code, or under an equivalent general license of an agreement state or the United States nuclear regulatory commission:
 - (1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under rule 3701:1-46-40 of the Administrative Code, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the

applicable acceptance criteria; or

- (2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (C)(2) of this rule, unless:
 - (a) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under rule 3701:1-46-40 of the Administrative Code; and
 - (b) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (C)(2) and (E)(2)(a) of this rule and any other criteria as may be required as a condition of the license issued under rule 3701:1-46-40 of the Administrative Code.

Replaces: 3701:1-46-41

Effective: 11/08/2015

Five Year Review (FYR) Dates: 11/01/2020

CERTIFIED ELECTRONICALLY

Certification

10/29/2015

Date

Promulgated Under: 119.03
Statutory Authority: 3748.01
Rule Amplifies: 3748.01
Prior Effective Dates: 10/20/2002, 1/20/08

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

3701:1-46-49 Registration of product information.

- (A) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the director for evaluation of radiation safety information about its product and for its registration.
- (B) The request for review must be made in duplicate and sent to the director at the following address:

"Ohio Department of Health
Bureau of Environmental Health and Radiation Protection
246 North High Street
Columbus, Ohio 43215"
- (C) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.
- (D) The director normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the director formulates reasonable standards and criteria with the help of the manufacturer or distributor. The director shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.
- (E) After completion of the evaluation, the director issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.
- (F) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:
 - (1) The statements and representations, including quality control program, contained in the request; and
 - (2) The provisions of the registration certificate.
- (G) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

- (1) Calibration and reference sources containing no more than:
 - (a) Thirty seven megabecquerels (one millicurie), for beta and/or gamma emitting radionuclides; or
 - (b) 0.37 megabecquerels (10 microcuries), for alpha emitting radionuclides; or
- (2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and
 - (a) The intended recipients are licensed under chapter 3701:1-40 of the Administrative Code or comparable provisions of another agreement state or the United States nuclear regulatory commission; or
 - (b) The recipients are authorized for research and development; or
 - (c) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than seven hundred forty gigabecquerels (twenty curies) of tritium or 7.4 gigabecquerels (two hundred millicuries) of any other radionuclide.
- (H) After the certificate is issued, the director may conduct an additional review as he/she determines is necessary to ensure compliance with current regulatory standards. In conducting the review, the director will complete his/her evaluation in accordance with criteria specified in this rule. The director may request such additional information as he/she considers necessary to conduct his/her review and the certificate holder shall provide the information as requested.
- (I) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the director shall request inactivation of the registration certificate. Such a request must be made to the director by an appropriate method listed in rule 3701:1-40-04 of the Administrative Code and must normally be made no later than two years after the initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within ninety days of this determination and briefly describe the circumstances of the delay.
- (J) If a distribution license is to be terminated in accordance with rule 3701:1-40-18 of the Administrative Code, the licensee shall request inactivation of its registration certificates associated with that distribution license before the director will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.
- (K) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

Replaces: 3701:1-46-49

Effective: 11/08/2015

R.C. 119.032 review dates: 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, 1/20/08, 12/1/12