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 equivalent agreement state regulations.

(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: 10/04/2010

R.C. 119.032 review dates: 06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

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Certification

09/24/2010

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Date

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

3701:1-46-08 **Americium-241 or radium-226 in the form of calibration or reference sources.**

(A) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of paragraphs (B) and (C) of this rule, americium-241 or radium-226 in the form of calibration or reference sources.

(B) The general license in paragraph (A) of this rule applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued pursuant to rule 3701:1-46-37 of the Administrative Code or in accordance with the specifications contained in a specific license issued to the manufacturer by the United States nuclear regulatory commission or another agreement state which authorizes manufacture of the sources for distribution to persons with a general license by the United States nuclear regulatory commission or another agreement state.

(C) The general license in paragraph (A) of this rule is subject to the provisions of paragraph (D) of 3701:1-40-08, paragraphs (A) to (C) of 3701:1-40-16, rules 3701:1-40-19 to 3701:1-40-21, and Chapter 3701:1-38 of the Administrative Code. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than one hundred eighty-five kilobecquerels (five microcuries) of americium-241 or radium-226 in such sources:

(2) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement for Am-241:

(a) The receipt, possession, use and transfer of this source, model __, serial no. __, are subject to a general license and the regulations of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

"CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE"

(Name of manufacturer or initial transferor)

Or for radium-226;

(b) The receipt, possession, use and transfer of this source, model_____, serial no. _____, are subject to a general license and the regulations of the United States nuclear regulatory commission or an agreement state. Do not remove this label.

"CAUTION - RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE."

(Name of manufacturer or initial transferor)

Sources generally licensed under the nuclear regulatory commission or an agreement state prior to January 19, 1975, may bear labels authorized by the United States nuclear regulatory commission regulations in effect on January 1, 1975.

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license pursuant to this chapter or from an agreement state, the United States nuclear regulatory commission to receive the source.

(4) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain either americium-241 or radium-226, as applicable which might otherwise escape during storage.

(5) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(D) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241 or radium-226.

(E) This general license does not authorize the export of calibration or reference sources containing americium-241 or radium-226.

Effective: 10/04/2010

R.C. 119.032 review dates: 06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

_____
Date

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

3701:1-46-11 **General license for use of radioactive material for certain in-vitro clinical or laboratory testing.**

(A) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (B) to (F) of this rule, the following radioactive materials in prepackaged units:

(1) Iodine-125, in units not exceeding three hundred seventy kilobecquerels (ten microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding three hundred seventy kilobecquerels (ten microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding three hundred seventy kilobecquerels (ten microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 1.85 megabecquerels (fifty microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding seven hundred forty kilobecquerels (twenty microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding three hundred seventy kilobecquerels (ten microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(7) Mock iodine-125 reference or calibration sources, in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and one hundred eighty-five becquerels (0.005 microcurie) of americium-241 each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(8) Cobalt-57, in units not exceeding three hundred seventy kilobecquerels (ten microcuries) each for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(B) A person shall not receive, acquire, possess, use, or transfer radioactive material under the general license established by paragraph (A) of this rule unless that person:

(1) Has filed the radioactive materials in-vitro testing form with the director; or

(2) Has a license that authorizes the medical use of radioactive material that was issued under rules for medical uses of radioactive material.

(C) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by paragraph (A) of this rule shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (A) of this rule, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 7.4 megabecquerels (two hundred microcuries).

(2) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the radioactive material only for the uses authorized by paragraph (A) of this rule.

(4) The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it by a license pursuant to this chapter, from the United States nuclear regulatory commission, or from an agreement state or transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in paragraph (A)(7) of this rule as required by rule 3701:1-38-19 of the Administrative Code.

(D) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to paragraph (A) of this rule:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of rule 3701:1-46-42 of the Administrative Code or in accordance with the provisions of a specific license issued by the United States nuclear regulatory commission or an agreement state that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, mock iodine-125, or cobalt-57 for distribution to persons generally licensed by the United States nuclear regulatory commission or an agreement state.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package: This radioactive material may be received,

acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in- vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority _____(name of manufacturer)

(E) The licensee possessing or using radioactive materials under the general license of paragraph (A) of this rule shall report in writing to the director any changes in the information furnished by the licensee in department form HEA-5518, "In-Vitro Testing With Radioactive Material Form." The report shall be furnished within thirty days after the effective date of such change.

(F) Any person using radioactive material pursuant to the general license of paragraph (A) of this rule is exempt from the requirements of Chapter 3701:1-38 of the Administrative Code with respect to radioactive materials covered by that general license, except that such persons using the mock iodine-125 described in paragraph (A)(7) of this rule shall comply with the provisions of paragraph (A) of rule 3701:1-38-19 of the Administrative Code and paragraphs (A) and (B) of rule 3701:1-38-21 of the Administrative Code.

Effective: 10/04/2010

R.C. 119.032 review dates: 06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

_____
Date

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

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 by rule 3701:1-46-46 of the Administrative Code.

Effective: 10/04/2010

R.C. 119.032 review dates: 06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

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Date

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

3701:1-46-38 **Calibration or reference sources containing americium-241 or radium-226: labeling of devices.**

(A) Each person licensed under rule 3701:1-46-37 of the Administrative Code shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include one of the following statements or a substantially similar statement which contains the information called for in one of the following statements:

(1) For americium-241:

The receipt, possession, use and transfer of this source, model __-, serial no. __-, are subject to a general license and the regulations of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

"CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE."

Name of manufacturer or initial transferor.

(2) For radium-226:

The receipt, possession, use and transfer of this source, model __-, serial no. __-, are subject to a general license and the regulations of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

"CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS RADIUM-226.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE."

Name of manufacturer or initial transferor.

(B) Sources 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.

Effective:	10/04/2010
R.C. 119.032 review dates:	06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

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Certification

09/24/2010

_____
Date

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

3701:1-46-39 **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 any such test discloses more than one hundred eighty-five becquerels (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under rule 3701:1-46-08 of the Administrative Code.

Effective: 10/04/2010

R.C. 119.032 review dates: 06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

_____
Date

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

3701:1-46-42 **Manufacture and distribution of radioactive material for certain in-vitro clinical or laboratory testing under general license.**

An application for a specific license to manufacturer or distribute radioactive material for use under the general license in rule 3701:1-46-11 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 radioactive material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(2) Iodine-131 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(3) Carbon-14 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(4) Hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerels (fifty microcuries) each.

(5) Iron-59 in units not exceeding 0.74 megabecquerel (twenty microcuries) each.

(6) Selenium-75 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(7) Mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and0.185 kilobecquerel (0.005 microcurie) of americium-241 each.

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(C) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (ten microcuries) of iodine-131, iodine-125, selenium-75, cobalt-57, or carbon-14; 1.85 megabecquerels (fifty microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (twenty microcuries) of iron-59; or mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; and

(2) Displaying the radiation symbol described in paragraph (A) of rule 3701:1-38-18 of the Administrative Code and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans or Animals."

(D) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
"The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)"

(E) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in paragraph (A) of rule 3701:1-38-19 of the Administrative Code.

Effective:	10/04/2010
R.C. 119.032 review dates:	06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

_____
Date

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

3701:1-46-43 **Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use.**

(A) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Chapter 3701:1-58 of the Administrative Code or equivalent regulations of an agreement state will be approved if:

(1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;

(2) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered with the United States food and drug administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 C.F.R. 207.20(a) (as published in the April 1, 2009 Code of Federal Regulations);

(b) Registered or licensed with a state agency as a drug manufacturer;

(c) Licensed as a pharmacy by a state board of pharmacy;

(d) Operating as a nuclear pharmacy within a federal medical institution~~.~~; or

(e) A positron emission tomography (PET) drug production facility registered with a state agency.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) The applicant satisfies the following labeling requirements:

(a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–-life greater than one hundred days, the time may be omitted.

(b) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can

be correlated with the information on the transport radiation shield label.

(B) A licensee described by paragraph (A)(2)(c) or (A)(2)(d) of this rule:

(1) May prepare radioactive drugs for medical use, as defined in rule 3701:1-38-01 of the Administrative Code, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (B)(2) and (B)(3) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in rule 3701:1-58-14 of the Administrative Code.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in rule 3701:1-58-01 of the Administrative Code,

(b) This individual meets the requirements specified in paragraph (B) of rule 3701:1-58-20 of the Administrative Code and rule 3701:1-58-22 of the Administrative Code and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (B)(4) of this rule.

(3) The actions authorized in paragraphs (B)(1) and (B)(2) of this rule are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in rule 3701:1-38-01 of the Administrative Code) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a government agency or federally recognized indian tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission.

(5) Shall provide to the director a copy of:

(a) Each individual's certification by a specialty board whose certification process has been recognized by the United States nuclear regulatory commission or an agreement state as specified in paragraph (A) of rule 3701:1-58-20 of the Administrative Code with the written attestation signed by a preceptor as required by paragraph (B)(2) of rule 3701:1-58-20 of the Administrative Code; or

(b) The United States nuclear regulatory commission or agreement state license; or

(c) The permit issued by a United States nuclear regulatory commission master materials licensee; or

(d) The permit issued by a licensee or United States nuclear regulatory commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission; and

(f) State pharmacy licensure or registration, no later than thirty days after the date that the licensee allows, under paragraphs (B)(2)(a) and (B)(2)(c) of this rule, the individual to work as an authorized nuclear pharmacist.

(C) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(D) Nothing in this rule relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs.

Effective:	10/04/2010
R.C. 119.032 review dates:	06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

_____
Date

Promulgated Under:	119.03
Statutory Authority:	3742.02, 3748.04
Rule Amplifies:	3748.04
Prior Effective Dates:	10/20/2002, 8/15/05, 1/20/08, 12/22/08

3701:1-46-46 **Prototype tests for calibration or reference sources containing americium-241 or radium-226.**

An applicant for a license pursuant to rule 3701:1-46-37 of the Administrative Code shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

-Prototype tests-

Initial measurement	The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.
Dry wipe test	The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.
Wet wipe test	The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.
Water soak test	The source shall be immersed in water at room temperature for a period of twenty-four consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.
Dry wipe test	On completion of the preceding tests in this rule, the dry wipe test described in this rule shall be repeated.
Observations	Removal of more than 0.185 kilobecquerel (0.005 microcurie) of radioactivity in any test prescribed by this rule shall be cause for rejection of the source design. Results of prototype tests submitted to the director shall be given in terms of radioactivity in becquerels (or metric multiple, thereof) and per cent of removal from the total amount of radioactive material deposited on the source.

Effective:	10/04/2010
R.C. 119.032 review dates:	06/28/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

_____
Certification

09/24/2010

_____
Date

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

3701:1-46-51 **General license for certain items and self-luminous products containing radium-226.**

(A) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (B), (C), and (D) of this rule, radium-226 contained in the following products manufactured prior to November 30, 2007:

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late nineteenth and early twentieth centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads;

(2) Intact timepieces containing greater than 0.037 megabecquerel (one microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

(3) Luminous items installed in air, marine, or land vehicles;

(4) All other luminous products, provided that no more than one hundred items are used or stored at the same location at any one time; and

(5) Small radium sources containing no more than 0.037 megabecquerel (one microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the department or the United States nuclear regulatory commission.

(B) Persons who acquire, receive, possess, use, or transfer radium-226 under the general license issued in paragraph (A) of this rule are exempt from the provisions of rules 3701:1-38-07, 3701:1-38-09 to 3701:1-38-18, 3701:1-38-20 to 3701:1-38-25 of the Administrative Code, to the extent that the receipt, possession, use, or transfer of radium-226 is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed in accordance with rule 3701:1-38-02 of the Administrative Code.

(C) Any person who acquires, receives, possesses, uses, or transfers radium-226 in accordance with the general license in paragraph (A) of this rule:

(1) Shall notify the department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the department in the manner specified in rule 3701:1-40-04 of the Administrative Code within thirty days.

(2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of in accordance with rule 3701:1-38-19 of the Administrative Code, or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the department.

(3) Shall not export products containing radium-226 except in accordance with United States nuclear regulatory commission regulations.

(4) Shall dispose of products containing radium-226:

(a) At a disposal facility authorized to dispose of radioactive material in accordance with Chapter 3701:1-54 of the Administrative Code or equivalent regulation of an agreement state or the United States nuclear regulatory commission;

(b) By transfer to a person authorized to receive radium-226 by a specific license issued in accordance with rule 3701:1-38-02 of the Administrative Code or equivalent regulations of an agreement state or the United States nuclear regulatory commission; or

(c) As otherwise approved by the department.

(5) Shall respond to written requests from the department 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 department, in the manner specified in rule 3701:1-40-04 of the Administrative Code, a written justification for the request.

(D) The general license in paragraph (A) of this rule does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

Effective:	10/04/2010
R.C. 119.032 review dates:	10/01/2015

CERTIFIED ELECTRONICALLY

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Certification

09/24/2010

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Date

Promulgated Under:	119.03
Statutory Authority:	3748.04
Rule Amplifies:	3748.04