

OHIO DEPARTMENT OF HEALTH

246 North High Street
Post Office Box 118
Columbus, Ohio 43216-0118

Telephone (614) 466-3543
www.odh.state.oh.us



BOB TAFT
Governor

J NICK BAIRD, M D
Director of Health

October 29, 2002

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mrs. Piccone:

Enclosed is a copy of the final revisions to the Ohio Department of Health Chapter 3701:1-46, General Licenses and Licenses for Manufacturing and Distribution effective October 20, 2002. The final regulations correspond to the following equivalent amendments to NRC's regulations: RATS ID # 2001-1.

We have incorporated the comments cited in your letter dated December 11, 2001 regarding our proposed version of these regulations.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

If you have any questions, please feel free to contact me at 614-644-2727.

Sincerely yours,

Handwritten signature of Roger L. Suppes in cursive.

Roger L. Suppes, Chief
Bureau of Radiation Protection

Enclosures:
As stated

02 NOV 13 PM 3:58

STP

STP-DD6 Template
RIBS DIST. SP07

Table of Contents
3701:1-46
General Licenses and Licenses for Manufacturing and Distribution

ODH Rule	NRC Rule	Title
46-02	31.1	Purpose and Scope
46-03	31.2	Terms and Conditions
46-04	31.3	Certain devices and equipment
DELETED	31.4	Information collection requirements: OMB approval
46-05	31.5	Certain measuring, gauging or controlling devices
46-06	31.6	License to install devices that are generally licensed
46-07	31.7	Luminous safety devices for use in aircraft
46-08	31.8	Americium-241 or radium in the form of calibration or reference sources
46-09	31.9	General license to own byproduct, accelerator produced material, or radium
46-10	31.10	General license for strontium 90 in ice detection devices
46-11	31.11	General license for use of either byproduct or accelerator produced material for certain in-vitro clinical or laboratory testing
46-12	31.12	Maintenance of records
DELETED	31.13	Violations
DELETED	31.14	Criminal penalties
46-02	32.1	Purpose and scope
46-01	32.2	Definitions
46-12	32.3	Maintenance of records
DELETED	32.8	Information collection requirements: OMB approval
46-13	32.11	Introduction of byproduct, accelerator produced material, or radium in exempt concentrations into products or materials and transfer of ownership or possession of accelerator produced material or radium in exempt concentrations: Requirements for license
46-14	32.12	Same: Records and material transfer reports
46-15	32.13	Same: Prohibition of introduction
46-16	32.14	Certain items containing byproduct , accelerator produced material or radium; requirements for license to apply
46-17	32.15	Same: Quality assurance, prohibition of transfer and labeling
46-18	32.16	Certain items containing byproduct, accelerator produced material or radium: Records and reports of transfer
46-19	32.17	Resins containing scandium-46 and designed for sand-consolidations in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution

Table of Contents
3701:1-46
General Licenses and Licenses for Manufacturing and Distribution

46-20	32.18		Manufacture of exempt quantities of byproduct, accelerator produced material or radium: Requirements for license
46-21	32.19		Same: Conditions of licenses
46-22	32.20		Same: Records and material transfer reports
46-23	32.21		Radioactive drug: manufacture, preparation of capsules containing carbon-14 urea each for "in-vivo" diagnostic use for humans to persons exempt from licensing; requirements for a license
46-24	32.21a		Same: Conditions of license
46-25	32.22		Self-luminous products containing tritium, krypton-85 and promethium-147: Requirements for license to manufacture, process, produce
46-26	32.23		Same: Safety criteria
46-26	32.24	Appendix	Same: Table of organ doses
DELETED	32.25		Conditions of licenses issued under 32.22: Quality control, labeling and reports of transfer
46-27	32.26		Gas and aerosol detectors containing byproduct, accelerator produced material or radium: Requirements for license to manufacture, process, produce or initially transfer
46-28	32.27		Same: Safety criteria
46-28	32.28	Appendix	Same: Table of organ doses
DELETED	32.29		Conditions of licenses issued under 32.26: Quality control, labeling and reports of transfer
46-29	32.40		Prototype tests for automobile lock illuminators
46-30	32.51		Byproduct, accelerator produced material, or radium contained in devices for use under rule 3701:1-46-05 of this Chapter: Requirements for license to manufacture or initially transfer
46-31	32.51a		Same: Conditions of licenses
46-32	32.52		Same: Material transfer reports and records
46-33	32.53		Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair, or initially transfer
46-34	32.54		Same: Labeling of devices
46-35	32.55		Same: Quality assurance; prohibition of transfer
46-36	32.56		Same: Material transfer reports
46-37	32.57		Calibration or reference sources containing americium-241 or radium: Requirements for license to manufacture or initially transfer
46-38	32.58		Same: Labeling of devices
46-39	32.59		Same: Leak testing of each source
DELETED	32.60		[Reserved]
46-40	32.61		Ice detection devices containing strontium-90: Requirements for license to manufacture or initially transfer

Table of Contents
3701:1-46
General Licenses and Licenses for Manufacturing and Distribution

46-41	32.62		Same: Quality assurance, prohibition of transfer
46-42	32.71		Manufacture and distribution of byproduct or accelerator produced material for certain in-vitro clinical or laboratory testing under general license
46-43	32.72		Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct or accelerator produced material for medical use under 10 CFR 35
46-44	32.74		Manufacture and distribution of sources or devices containing byproduct or accelerator produced material for medical use
46-45	32.101		Prototype tests for luminous safety devices for use in aircraft
46-46	32.102		Prototype tests for calibration or reference sources containing americium-241 or radium
46-47	32.103		Prototype tests for ice detection devices containing strontium-90
46-48	32.110		Acceptance sampling procedures under certain specific licenses
46-49	32.210		Registration of product information
DELETED	32.301		Violations
DELETED	32.303		Criminal penalties



Ohio Administrative Code

Chapter 3701:1-46

General Licenses and Licenses for Manufacturing and Distribution

These files are in .PDF format. The free [Adobe Acrobat Viewer](#) is required to view them.

File Size	Rule No.	Title
5.11 KB	3701:1-46-01	Definitions
5.73 KB	3701:1-46-02	Purpose and scope
4.94 KB	3701:1-46-03	Terms and conditions
5.36 KB	3701:1-46-04	Certain devices and equipment
15.65 KB	3701:1-46-05	Certain measuring, gauging or controlling devices
5.23 KB	3701:1-46-06	License to install devices that are generally licensed
4.10 KB	3701:1-46-07	Luminous safety devices for use in aircraft
7.62 KB	3701:1-46-08	Americium-241 or radium in the form of calibration or refere
4.88 KB	3701:1-46-09	General license to own byproduct, accelerator produced mat
6.36 KB	3701:1-46-10	General License for strontium-90 in ice detection devices
10.07 KB	3701:1-46-11	General license for use of either byproduct or accelerator pro material for certain in vitro clinical or laboratory testing
5.08 KB	3701:1-46-12	Maintenance of records
6.53 KB	3701:1-46-13	Introduction of byproduct, accelerator produced material, or exempt concentrations into products or materials, and trans ownership or possession of accelerator produced material or exempt concentrations; requirements for license
37.18 KB	Appendix A	
6.47 KB	3701:1-46-14	Introduction of byproduct, accelerator produced material, or exempt concentrations into products or materials, and trans ownership or possession of accelerator produced material or exempt concentrations; records and material transfer report
5.08 KB	3701:1-46-15	Introduction of byproduct, accelerator produced material, or exempt concentrations into products or materials, and trans ownership or possession of accelerator produced material or exempt concentrations; prohibition of introduction
7.99 KB	3701:1-46-16	Certain items containing byproduct, accelerator produced ma radium; requirements for license to apply
6.74 KB	3701:1-46-17	Certain items containing byproduct, accelerator produced ma radium; quality assurance, prohibition of transfer, and labeli
7.71 KB	3701:1-46-18	Certain items containing by product, accelerator produced m radium; records and reports of transfer
6.01 KB	3701:1-46-19	Resins containing scandium-46 and designed for sand-conso wells: requirements for license to manufacture, or initially t

		or distribution
6.27 KB	<u>3701:1-46-20</u>	Manufacture of exempt quantities of byproduct, accelerator material, or radium: requirements for license
8.40 KB	<u>3701:1-46-21</u>	Manufacture of exempt quantities of byproduct, accelerator material, or radium: conditions of licenses
5.66 KB	<u>3701:1-46-22</u>	Manufacture of exempt quantities of byproduct, accelerator material, or radium: records and material transfer reports
6.48 KB	<u>3701:1-46-23</u>	Radioactive drug: manufacture, preparation of capsules cont 14 urea each for in-vivo diagnostic use for humans to person licensing; requirements for a license
5.55 KB	<u>3701:1-46-24</u>	Radioactive drug: manufacture, preparation of capsules cont 14 urea each for in-vivo diagnostic use for humans to person licensing: conditions of license
9.51 KB	<u>3701:1-46-25</u>	Self-luminous products containing tritium, krypton-85 or pro requirements for license to manufacture, process, produce
6.50 KB 6.42 KB	<u>3701:1-46-26</u> Appendix A	Self-luminous products containing tritium, krypton-85 or pro 147:safety criteria
7.99 KB	<u>3701:1-46-27</u>	Gas and aerosol detectors containing byproduct, accelerator material, or radium: requirements for license to manufacture, produce, or initially transfer
6.43 KB 5.73 KB	<u>3701:1-46-28</u> Appendix A	Gas and aerosol detectors containing byproduct, accelerator material, or radium: safety criteria
6.72 KB	<u>3701:1-46-29</u>	Schedule A - prototype tests for automobile lock illuminators
10.50 KB	<u>3701:1-46-30</u>	Byproduct, accelerator produced material, or radium contain for use under rule 3701:1-46-05 of this chapter; requirements to manufacture, or initially transfer
6.85 KB	<u>3701:1-46-31</u>	Byproduct, accelerator produced material, or radium contain for use under rule 3701:1-46-05 of this chapter; conditions
9.21 KB	<u>3701:1-46-32</u>	Byproduct, accelerator produced material, or radium contain for use under rule 3701:1-46-05 of this chapter; material transfer and records
6.78 KB	<u>3701:1-46-33</u>	Luminous safety devices for use in aircraft: requirements for manufacture, assemble, repair or initially transfer
6.81 KB	<u>3701:1-46-34</u>	Luminous safety devices for use in aircraft: labeling of devices
7.11 KB	<u>3701:1-46-35</u>	Luminous safety devices for use in aircraft: quality assurance of transfer
5.23 KB	<u>3701:1-46-36</u>	Luminous safety devices for use in aircraft: material transfer
6.53 KB	<u>3701:1-46-37</u>	Calibration or reference sources containing americium-241 or requirements for license to manufacture or initially transfer
5.97 KB	<u>3701:1-46-38</u>	Calibration or reference sources containing americium-241 or labeling of devices
5.24KB	<u>3701:1-46-39</u>	Calibration or reference sources containing americium-241 or testing of each source
7.24 KB	<u>3701:1-46-40</u>	Ice detection devices containing strontium-90: requirements for manufacture or initially transfer
7.18 KB	<u>3701:1-46-41</u>	Ice detection devices containing strontium-90: quality assurance prohibition of transfer
8.02 KB	<u>3701:1-46-42</u>	Manufacture and distribution of byproduct or accelerator produced

		for certain in vitro clinical or laboratory testing under genera
10.47 KB	3701:1-46-43	Manufacture, preparation, or transfer for commercial distribu radioactive drugs containing byproduct or accelerator produc medical use under 10 CFR 35
9.64 KB	3701:1-46-44	Manufacture and distribution of sources or devices containin accelerator produced material for medical use
12.90 KB	3701:1-46-45	Prototype tests for luminous safety devices for use in airconf
7.11 KB	3701:1-46-46	Prototype tests for calibration or reference sources containin 241 or radium
7.59 KB	3701:1-46-47	Prototype tests for ice detection devices containing strontium
12.36 KB	3701:1-46-48	Acceptance sampling procedures under certain specific licens
6.42 KB	3701:1-46-49	Registration of product information

 [BACK](#)

Last Updated: 10/18/02

[Home](#) | [Search](#) | [SiteMap](#)

3701:1-46-01 **Definitions.**

Terms defined in rules 3701:1-38-01 and 3701:1-40-01 and Chapter 3701:1-50 of the Administrative Code shall have the same meaning when used in this chapter except terms redefined within a given rule for use within that rule only and additionally, as used in this chapter:

- (A) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.
- (B) "Consumer's Risk" means for a given sampling plan, the probability of accepting a lot, when the sampling plan is applied to a submitted lot or process of a given relatively poor quality, whichever is applicable.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-02 **Purpose and scope.**

- (A) This chapter establishes general licenses for the possession and use of byproduct, accelerator produced material, or radium and a general license for ownership of byproduct, accelerator produced material, or radium. Specific provisions of Chapter 3701:1-40 of the Administrative Code are applicable to general licenses established by this part. 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 byproduct, accelerator produced material, or radium for sale or distribution to persons generally licensed under Chapters 3701:1-46 of the Administrative Code or 10 C.F.R. 35 as specified in appendix A to rule 3701-39-02.1 of the Administrative Code or equivalent agreement state or NARM licensing 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 byproduct, accelerator produced material, or radium 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 & 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 or for NARM, a NARM licensing 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 date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-03 **Terms and conditions.**

The general licenses provided in this chapter are subject to the provisions of rules 3701:1-38-09, paragraph (D) of 3701:1-40-08, paragraphs (A) to (C) of 3401:1-40-16, 3701:1-40-19, 3701:1-40-20, 3701:1-40-21, and 3701:1-38-06 of the Administrative Code and Chapter 3701:1-38 of the Administrative Code unless indicated otherwise in the specific provision of the general license. Attention is directed particularly to the provisions of the regulations in Chapter 3701:1-38 of the Administrative Code which relate to the labeling of containers.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-04

Certain devices and equipment.

A general license is hereby issued to transfer, receive, acquire, own, possess and use byproduct, accelerator produced material, or radium incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to him by the department.

- (A) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 megabecquerels (five hundred microcuries) of polonium-210 per device.
- (B) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 megabecquerels (five hundred microcuries) of polonium- 210 per device or of a total of not more than 1.85 gigabecquerels (fifty millicuries) of hydrogen -3 (tritium) per device.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-05

Certain measuring, gauging or controlling devices.

- (A) A general license is hereby issued to commercial and industrial firms and 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), (C) and (D) of this rule, byproduct, accelerator produced material, or radium 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. Persons possessing byproduct, accelerator produced material, or radium in devices under the general license issued before January 15, 1975, may continue to possess, use or transfer that material in accordance with the requirements of regulations in effect on January 14, 1975.
- (B)
- (1) The general license in paragraph (A) of this rule applies only to byproduct, accelerator produced material, or radium contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in rule 3701:1-46-30 of the Administrative Code in accordance with:
 - (a) A specific license issued under rule 3701:1-46-30 of the Administrative Code; or
 - (b) An equivalent specific license issued by an agreement state or NARM licensing state;
 - (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 licenses 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 byproduct, accelerator produced material, or radium 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 Chapter 3701:1-40 and this chapter of the Administrative Code or from an agreement state, NARM licensing 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 microcuries) or more removable radioactive material. The device may not be operated until it has been repaired using requirements in the instruction manual, 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, NARM licensing state or the United States nuclear regulatory commission. The device may be disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device. 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 byproduct, accelerator produced material or radium;
- (7) Shall not export the device containing byproduct, accelerator produced material, or radium 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 Chapters 3701:1-40 and this chapter of the Administrative Code, utilizing a licensed broker or other authorized waste collection, or equivalent regulations of an agreement state, NARM licensing state, United States nuclear regulatory commission, or as approved under paragraph (C)(8)(c) of this rule.
 - (b) Shall furnish a report to the director within thirty days after the transfer of a device to a specific licensee. A report is not required if the device is transferred to the specific licensee in order to obtain a replacement device from the same specific licensee. 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.
- (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 department:
 - (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)(11) 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 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.
- (12)
- (a) Shall report, in accordance with paragraphs (C)(12)(b) and (c) of this rule, devices containing at least three hundred seventy MBq (ten mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, thirty seven MBq (one mCi) of cobalt-60, 3.7 kBq (0.1 μ Ci) of radium, or thirty seven MBq (one mCi) 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)(12)(c)(iv), represents a separate general license.
 - (b) If in possession of a device meeting the criteria of paragraph (C)(12)(a) of this rule, shall report these devices annually to the director and is subject to the fees in paragraph (U) of rule 3701:1-38-02 of the Administrative Code. Reporting must be done by verifying, correcting, and/or adding to the information contained in a request provided by 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)(12)(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 radioisotope and activity (as indicated on the label).
 - (iii) Name and telephone number of the responsible person designated as a representative of the general licensee under paragraph (C)(11) of this rule.
 - (iv) Address 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.
 - (vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
- (13) Shall report changes of address (including change in name of general licensee) to the director within thirty days of the effective date of the change.
- (14) 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) All portable devices containing radioactive material, used within the state of Ohio, shall be licensed in accordance with rules 3701:1-38-02 and paragraph (I) of rule 3701:1-40-14 of the Administrative Code.

(F) The general license in paragraph (A) of this rule does not authorize the manufacture or import of devices containing byproduct, accelerator produced material or radium.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-06

License to install devices that are generally licensed.

Any person who holds a specific license issued by the United States nuclear regulatory commission, an agreement state, or NARM licensing state authorizing the holder to manufacture, install, or service a device described in rule 3701:1-46-05 of the Administrative Code is hereby granted a general license to install and service such device provided that:

- (A) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued such person by the United States nuclear regulatory commission, an agreement state, or NARM licensing state and requirements of paragraph (C)(2) of rule 3701:1-38-02 of the Administrative Code.
- (B) Such person assures that any labels required to be affixed to the device under regulations of the United States nuclear regulatory commission, an agreement state, or NARM licensing state which licensed the manufacturer of the device, bear a statement that removal of the label is prohibited.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-07

Luminous safety devices for use in aircraft.

- (A) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 0.37 terabecquerels (ten curies) of tritium or 11.1 gigabecquerels (three hundred millicuries) of promethium-147 and that each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions of rule 3701:1-46-33 of this chapter or manufactured or assembled in accordance with a specific license issued by the United States nuclear regulatory commission or an agreement state which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the United States nuclear regulatory commission or an agreement state.
- (B) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this rule are exempt from the requirements of chapter 3701:1-38 of the Administrative Code except that they shall comply with the provisions of paragraphs (A) and (B) of rule 3701:1-38-21 of the Administrative Code.
- (C) This general license does not authorize the manufacture, assembly, repair or import of luminous safety devices containing tritium or promethium-147.
- (D) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.
- (E) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-08 Americium-241 or radium 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 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 this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by the United States nuclear regulatory commission, another agreement state, or NARM licensing state for radium which authorizes manufacture of the sources for distribution to persons with a general license by the United States nuclear regulatory commission, another agreement state, or NARM licensing state for radium.
- (C) The general license in paragraph (A) of this rule is subject to the provisions of rules 3701:1-38-09, paragraph (D) of 3701:1-40-08, paragraphs (A) to (C) of 3701:1-40-16, 3701:1-40-19, 3701:1-40-20, 3701:1-40-21, and 3701:1-38-06 of the Administrative Code 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 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:
 - (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;

- (b) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a NARM licensing state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS RADIUM.
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 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, or a NARM licensing state 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, 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.
- (E) This general license does not authorize the export of calibration or reference sources containing americium-241 or radium.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-09

General license to own byproduct, accelerator produced material, or radium.

A general license is hereby issued to own byproduct, accelerator produced material, or radium without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct or accelerator produced material, except as authorized in a specific license.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification

10/10/2002

Date

Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: None

3701:1-46-10

General license for strontium-90 in ice detection devices.

- (A) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 megabecquerels (fifty microcuries) of strontium-90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to rule 3701:1-46-40 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by the United States nuclear regulatory commission or an agreement state which authorizes manufacture of the ice detection devices for distribution to persons with a general license issued by the United States nuclear regulatory commission or an agreement state.
- (B) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph (A) of this section:
- (1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to rule 3701:1-38-02 and Chapters 3701:1-40 and 3701:1-46 of the Administrative Code or from the United States nuclear regulatory commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of paragraph (A) of rule 3701:1-38-19 of the Administrative Code.
 - (2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;
 - (3) Are exempt from the requirements of Chapter 3701:1-38 of the Administrative Code except that such persons 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.
- (C) The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium-90 in ice detection devices.

Effective date: October 20, 2002

R.C. 119.032 review dates: 10/1/2007

CERTIFIED ELECTRONICALLY

Certification