3701:1-40-03 **Activities requiring license.**

Unless otherwise exempt as provided in rule 3701-39-02.1 of the Administrative Code, or unless possession is solely for the purpose of transportation, no person shall handle or possess (including manufacture, produce, acquire, or own) or dispose of (including closure, decommissioning, reclamation, or long-term surveillance or care) radioactive material except as authorized in a specific or general license issued in accordance with this chapter, or other chapters of the Administrative Code adopted pursuant to Chapter 3748. of the Revised Code and rule 3701:1-38-02 of the Administrative Code.

Replaces:	3701:1-40-23
Effective:	10/04/2010
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09/24/2010

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Statutory Authority:	3748.02, 3748.04
Rule Amplifies:	3748.04
Prior Effective Dates;	722/2001, 8/15/05

3701:1-40-09 **Certain items containing radioactive material**.

(A) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and Chapters 3701:11-38, 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(a) Nine hundred twenty-five megabecquerels (twenty-five millicuries) of tritium per timepiece,

(b) One hundred eighty-five megabecquerels (five millicuries) of tritium per hand,

(c) Five hundred fifty-five megabecquerels (fifteen millicuries) of tritium per dial (bezels when used shall be considered as part of the dial),

(d) 3.7 megabecquerels (one hundred microcuries) of promethium-147 per watch or 7.4 megabecquerels (two hundred microcuries) of promethium-147 per any other timepiece,

(e) Seven hundred forty kilobecquerels (twenty microcuries) of promethium-147 per watch hand or one thousand four hundred eighty kilobecquerels (forty microcuries) of promethium-147 per other timepiece hand,

(f) Two thousand two hundred twenty kilobecquerels (sixty microcuries) of promethium-147 per watch dial or 4.44 megabecquerels (one hundred twenty microcuries) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial), and

(g) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through fifty milligrams per square centimeter of absorber:

(i) For wrist watches, one nanogray (0.1 millirad) per hour at ten centimeters from any surface,

(ii) For pocket watches, one nanogray (0.1 millirad) per hour at one centimeter from any surface, and

(iii) For any other timepiece, two nanogray (0.2 millirad) per hour at ten centimeters from any surface.

(h) Thirty-seven kilobecquerels (one microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(2) Balances of precision containing not more than thirty-seven megabecquerels (one millicurie) of tritium per balance or not more than 18.5 megabecquerels (0.5 millicurie) of tritium per balance part manufactured before December 17, 2007.

(3) Marine compasses containing not more than 27.75 gigabecquerels (seven hundred fifty millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 gigabecquerels (two hundred fifty millicuries) of tritium gas manufactured before December 17, 2007.

(4) Ionization chamber smoke detectors containing not more than thirty-seven kilobecquerels (one microcurie) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(5) Electron tubes: provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

(a) 5.55 gigabecquerels (one hundred fifty millicuries) of tritium per microwave receiver protector tube or three hundred seventy megabecquerels (ten millicuries) of tritium per any other electron tube;

(b) Thirty-seven kilobecquerels (one microcurie) of cobalt-60;

(c) One hundred eighty-five kilobecquerels (five microcuries) of nickel-63;

(d) One thousand one hundred ten kilobecquerels (thirty microcuries) of krypton-85;

(e) One hundred eighty-five kilobecquerels (five microcuries) of cesium-137; or

(f) One thousand one hundred ten kilobecquerels (thirty microcuries) of promethium-147;

And provided further, that the levels of radiation from each electron tube containing radioactive material do not exceed ten nanogray (one millirad) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this paragraph, electron tubes include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(6) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(a) Each source contains no more than one exempt quantity as set forth in the appendix to rule 3701:1-40-11 of the Administrative Code; and

(b) Each instrument contains no more than ten exempt quantities. For the purposes of this paragraph, an instrument's source may contain either one type or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in the appendix to rule 3701:1-40-11 of the Administrative Code, provided that the sum of such fractions shall not exceed unity.

(c) For purposes of this paragraph, 1.85 kilobecquerels (0.05 microcurie) of americium-241 is considered an exempt quantity under the appendix to rule 3701:1-40-11 of the Administrative Code.

(B) Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in paragraph (A) of this rule, or who desires to initially transfer for sale or distribution such products containing radioactive material, shall apply for a specific license issued by the United States nuclear regulatory commission.

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3701:1-40-11 Exempt quantities.

(A) Except as provided in paragraphs (C) to (E) of this rule, any person is exempt from requirements set forth in this chapter and from the rules in Chapters 3701:1-46, 3701:1-48, 3701:1-49, and 3701:1-52 of the Administrative Code, to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the appendix to this rule.

(B) Any person who possesses radioactive material received or acquired before September 25, 1971, under the general license then provided in 10 C.F.R. section 31.4 or similar general license of a state, is exempt from the requirements for a license set forth in this chapter and from the rules in Chapters 3701:1-46, 3701:1-48, 3701:1-49, and 3701:1-52 of the Administrative Code, to the extent that this person possesses, uses, transfers, or owns radioactive material.

(C) This rule does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of radioactive material or the incorporation of radioactive material into products intended for commercial distribution.

(D) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in the appendix to this rule, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this chapter or equivalent regulations of an agreement state or the United States nuclear regulatory commission, except in accordance with a license, issued by the United States nuclear regulatory commission, which states that the radioactive material may be transferred by the licensee to persons exempt under this rule or the equivalent regulations of an agreement state or the United States nuclear regulatory commission.

(E) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in the appendix to this rule, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

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Rule Amplifies:	3748.04, 3748.06, 3748.07
Prior Effective Dates;	7/22/2001, 8/15/05, 5/11/09

Appendix

Exempt Quantities

Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Antimony-122 (Sb-122)	3700	100
Antimony-124 (Sb-124)	370	10
Antimony-125 (Sb-125)	370	10
Arsenic-73 (As-73)	3700	100
Arsenic-74 (As-74)	370	10
Arsenic-76 (As-76)	370	10
Arsenic-77 (As-77)	3700	100
Barium-131 (Ba-131)	370	10
Barium-133 (Ba-133)	370	10
Barium-140 (Ba-140)	370	10
Bismuth-210 (Bi-210)	37	1
Bromine-82 (Br-82)	370	10
Cadmium-109 (Cd-109)	370	10
Cadmium-115m (Cd-115m)	370	10
Cadmium-115 (Cd-115)	3700	100
Calcium-45 (Ca-45)	370	10
Calcium-47 (Ca-47)	370	10
Carbon-14 (C-14)	3700	100
Cerium-141 (Ce-141)	3700	100
Cerium-143 (Ce-143)	3700	100
Cerium-144 (Ce-144)	37	1
Cesium-129 (Cs-129)	3700	100
Cesium-131 (Cs-131)	37000	1000
Cesium-134m (Cs-134m)	3700	100
Cesium-134 (Cs-134)	37	1

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Cesium-135 (Cs-135)	370	10
Cesium-136 (Cs-136)	370	10
Cesium-137 (Cs-137)	370	10
Chlorine-36 (Cl-36)	370	10
Chlorine-38 (Cl-38)	370	10
Chromium-51 (Cr-51)	37000	1000
Cobalt-57 (Co-57)	3700	100
Cobalt-58m (Co-58m)	370	10
Cobalt-58 (Co-58)	370	10
Cobalt-60 (Co-60)	37	1
Copper-64 (Cu-64)	3700	100
Dysprosium-165 (Dy-165)	370	10
Dysprosium-166 (Dy-166)	3700	100
Erbium-169 (Er-169)	3700	100
Erbium-171 (Er-171)	3700	100
Europium-152 (Eu-152) 9.2 h	3700	100
Europium-152 (Eu-152) 13 yr	37	1
Europium-154 (Eu-154)	37	1
Europium-155 (Eu-155)	370	10
Fluorine-18 (F-18)	37000	1000
Gadolinium-153 (Gd-153)	370	10
Gadolinium-159 (Gd-159)	3700	100
Gallium-67 (Ga-67)	3700	100
Gallium-72 (Ga-72)	370	10
Germanium-68 (Ge-68)	370	10
Germanium-71 (Ge-71)	3700	100
Gold-195 (Au-195)	370	10

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Gold-198 (Au-198)	3700	100
Gold-199 (Au-199)	3700	100
Hafnium-181 (Hf-181)	370	10
Holmium-166 (Ho-166)	3700	100
Hydrogen-3 (H-3)	37000	1000
Indium-111 (In-111)	3700	100
Indium-113m (In-113m)	3700	100
Indium-114m (In-114m)	370	10
Indium-115m (In-115m)	3700	100
Indium-115 (In-115)	370	10
Iodine-123 (I-123)	3700	100
Iodine-125 (I-125)	37	1
Iodine-126 (I-126)	37	1
Iodine-129 (I-129)	3.7	0.1
Iodine-131 (I-131)	37	1
Iodine-132 (I-132)	370	10
Iodine-133 (I-133)	37	1
Iodine-134 (I-134)	370	10
Iodine-135 (I-135)	370	10
Iridium-192 (Ir-192)	370	10
Iridium-194 (Ir-194)	3700	100
Iron-52 (Fe-52)	370	10
Iron-55 (Fe-55)	3700	100
Iron-59 (Fe-59)	370	10
Krypton-85 (Kr-85)	3700	100
Krypton-87 (Kr-87)	370	10
Lanthanum-140 (La-140)	370	10

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Lutetium-177 (Lu-177)	3700	100
Manganese-52 (Mn-52)	370	10
Manganese-54 (Mn-54)	370	10
Manganese-56 (Mn-56)	370	10
Mercury-197m (Hg-197m)	3700	100
Mercury-197 (Hg-197)	3700	100
Mercury-203 (Hg-203)	370	10
Molybdenum-99 (Mo-99)	3700	100
Neodymium-147 (Nd-147)	3700	100
Neodymium-149 (Nd-149)	3700	100
Nickel-59 (Ni-59)	3700	100
Nickel-63 (Ni-63)	370	10
Nickel-65 (Ni-65)	3700	100
Niobium-93m (Nb-93m)	370	10
Niobium-95 (Nb-95)	370	10
Niobium-97 (Nb-97)	370	10
Osmium-185 (Os-185)	370	10
Osmium-191m (Os-191m)	3700	100
Osmium-191 (Os-191)	3700	100
Osmium-193 (Os-193)	3700	100
Palladium-103 (Pd-103)	3700	100
Palladium-109 (Pd-109)	3700	100
Phosphorus-32 (P-32)	370	10
Platinum-191 (Pt-191)	3700	100
Platinum-193m (Pt-193m)	3700	100
Platinum-193 (Pt-193)	3700	100
Platinum-197m (Pt-197m)	3700	100

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Platinum-197 (Pt-197)	3700	100
Polonium-210 (Po-210)	3.7	0.1
Potassium-42 (K-42)	370	10
Potassium-43 (K-43)	370	10
Praseodymium-142 (Pr-142)	3700	100
Praseodymium-143 (Pr-143)	3700	100
Promethium-147 (Pm-147)	370	10
Promethium-149 (Pm-149)	370	10
Radium-224,-226,-228 (Ra-224,-226,-228)	3.7	0.1
Rhenium-186 (Re-186)	3700	100
Rhenium-188 (Re-188)	3700	100
Rhodium-103m (Rh-103m)	3700	100
Rhodium-105 (Rh-105)	3700	100
Rubidium-81 (Rb-81)	370	10
Rubidium-86 (Rb-86)	370	10
Rubidium-87 (Rb-87)	370	10
Ruthenium-97 (Ru-97)	3700	100
Ruthenium-103 (Ru-103)	370	10
Ruthenium-105 (Ru-105)	370	10
Ruthenium-106 (Ru-106)	37	1
Samarium-151 (Sm-151)	370	10
Samarium-153 (Sm-153)	3700	100
Scandium-46 (Sc-46)	370	10
Scandium-47 (Sc-47)	3700	100
Scandium-48 (Sc-48)	370	10
Selenium-75 (Se-75)	370	10

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Silicon-31 (Si-31)	3700	100
Silver-105 (Ag-105)	370	10
Silver-110m (Ag-110m)	37	1
Silver-111 (Ag-111)	3700	100
Sodium-22 (Na-22)	370	10
Sodium-24 (Na-24)	370	10
Strontium-85 (Sr-85)	370	10
Strontium-89 (Sr-89)	37	1
Strontium-90 (Sr-90)	3.7	0.1
Strontium-91 (Sr-91)	370	10
Strontium-92 (Sr-92)	370	10
Sulphur-35 (S-35)	3700	100
Tantalum-182 (Ta-182)	370	10
Technetium-96 (Tc-96)	370	10
Technetium-97m (Tc-97m)	3700	100
Technetium-97 (Tc-97)	3700	100
Technetium-99m (Tc-99m)	3700	100
Technetium-99 (Tc-99)	370	10
Tellurium-125m (Te-125m)	370	10
Tellurium-127m (Te-127m)	370	10
Tellurium-127 (Te-127)	3700	100
Tellurium-129m (Te-129m)	370	10
Tellurium-129 (Te-129)	3700	100
Tellurium-131m (Te-131m)	370	10
Tellurium-132 (Te-132)	370	10
Terbium-160 (Tb-160)	370	10
Thallium-200 (Ti-200)	3700	100

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Thallium-201 (Tl-201)	3700	100
Thallium-202 (Tl-202)	3700	100
Thallium-204 (Tl-204)	370	10
Thulium-170 (Tm-170)	370	10
Thulium-171 (Tm-171)	370	10
Tin-113 (Sn-113)	370	10
Tin-125 (Sn-125)	370	10
Tungsten-181 (W-181)	370	10
Tungsten-185 (W-185)	370	10
Tungsten-187 (W-187)	3700	100
Vanadium-48 (V-48)	370	10
Xenon-131m (Xe-131m)	37000	1,000
Xenon-133 (Xe-133)	3700	100
Xenon-135 (Xe-135)	3700	100
Ytterbium-175 (Yb-175)	3700	100
Yttrium-87 (Y-87)	370	10
Yttrium-88 (Y-88)	370	10
Yttrium-90 (Y-90)	370	10
Yttrium-91 (Y-91)	370	10
Yttrium-92 (Y-92)	3700	100
Yttrium-93 (Y-93)	3700	100
Zinc-65 (Zn-65)	370	10
Zinc-69m (Zn-69m)	3700	100
Zinc-69 (Zn-69)	37000	1000
Zirconium-93 (Zr-93)	370	10
Zirconium-95 (Zr-95)	370	10
Zirconium-97 (Zr-97)	370	10

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Radionuclide	Kilobecquerels (kBq)	Microcuries (µCi)
Any radioactive material not listed above other than alpha emitting radioactive material.	3.7	0.1

3701:1-40-13 **Gas and aerosol detectors containing radioactive material.**

(A) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, a person is exempt from license requirements set forth in this chapter or Chapters 3701:1-38, 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license for manufacture and distribution issued pursuant to rule 3701:1-46-27 of the Administrative Code, which license authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 C.F.R. 32.26, as published in the January 1, 2007, Code of Federal Regulations, authorizing distribution to persons exempt from regulatory requirements.

(B) A person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to paragraph (A) of this rule, shall apply for a license for manufacture and distribution pursuant to rule 3701:1-46-27 of the Administrative Code, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to paragraph (A) of this rule or equivalent regulations of an agreement state or the United States nuclear regulatory commission.

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3701:1-40-14 Application for specific licenses.

(A) An applicant for a license to receive and possess radioactive material shall apply in accordance with rule 3701:1-38-02 of the Administrative Code and this chapter on a form prescribed by the director. The original application shall be filed with the director. Information contained in previous applications, statements or reports filed with the director may be incorporated by reference, provided that the reference is clear, specific, and has been on file with the department for not more than two licensing periods, and provided that the item being referenced in the document is being referenced without change.

(B) The director may at any time after the filing of the original application require additional information from the applicant in order to determine whether a license should be issued or whether a current license should be modified or revoked.

(C) Each application shall be signed by the applicant or a person duly authorized to act for the applicant.

(D) An application for a license to receive and possess radioactive material for the conduct of any activity which the director has determined pursuant to rule 3701:1-40-36 of the Administrative Code could potentially affect the quality of the environment shall be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any environmental report required pursuant to rule 3701:1-40-36 of the Administrative Code.

(E) An application for a specific license other than broad scope as defined in rule 3701:1-40-23 of the Administrative Code to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

(1) Identify the source or device by manufacturer and model number as registered in the sealed source and device registry of the United States nuclear regulatory commission in accordance with sealed source and device registry requirements contained in rule 3701:1-46-49 of the Administrative Code, or with equivalent requirements from an agreement state or the United States nuclear regulatory commission; or

(2) Contain the information specified in sealed source and device registry requirements contained in paragraph (C) of rule 3701:1-46-49 of the Administrative Code so that the department is able to perform the review: or

(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007, that are not registered with the director in accordance with rule 3701:1-46-49 of the Administrative Code or equivalent requirements from an agreement state or the United States nuclear regulatory commission, and for which the applicant is unable to provide all categories of information specified in rule 3701:1-46-49 of the Administrative Code, the applicant must provide:

(a) All available information identified in rule 3701:1-46-49 of the Administrative Code concerning the source, and, if applicable, the device; and

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(F) In the case of an application for a license specified in rule 3701:1-40-16 of the Administrative Code, or an application for a specific license specified in Chapters 3701:1-46, 3701:1-48, or 3701:1-58 of the Administrative Code, the applicant shall provide a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

(G) Requirement for an emergency response plan:

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities specified in the appendix to this rule shall contain either:

(a) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 sievert (one rem) TEDE or 0.05 sievert (five rem) to the thyroid; or

(b) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation of the need to submit an emergency plan under this paragraph:

(a) The radioactive material is physically separated so that only a portion of the material could be involved in an accident;

(b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(c) The release fraction in the respirable size range would be lower than the release fraction specified in the appendix to this rule due to the chemical or physical form of the material;

(d) The solubility of the radioactive material would reduce the dose received;

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than the limit specified in the appendix to this rule;

(f) Operating restrictions or procedures would prevent a release fraction as large as that shown in the appendix to this rule; or

(g) Other factors appropriate for the specific facility as determined by the director.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (G)(1)(b) of this rule shall include the following information:

(a) A brief description of the licensee's facility and the area near the site.

(b) An identification of each type of possible radioactive material accident which may require protective action.

(c) A classification system for classifying an accident as either an alert or a site area emergency.

(d) Identification of the means of detecting each type of accident in a timely manner.

(e) A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(f) A brief description of the methods and equipment to assess releases of byproduct and accelerator produced materials.

(g) A brief description of the responsibilities of the licensee's personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the department, and identification of personnel responsible for developing, maintaining, and updating the plan.

(h) A commitment to, and a brief description of, the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that in the event that some personnel, parts of the facility, or some equipment is not available, that unavailability will not prevent such notification and coordination. The licensee shall also commit to notifying the department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements of the "Emergency Planning and Community Right-to-Know Act of 1986", Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(i) A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the department.

(j) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond

to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. The training also shall thoroughly prepare site personnel for their responsibilities in the event of an accident, including training on the emergency scenarios postulated as most probable for the specific site, and the use of team training for such scenarios.

(k) A brief description of the means of restoring the facility to a safe condition after an accident.

(l) Provisions for conducting quarterly communication checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communication checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(m) A certification that the applicant has met all responsibilities under the "Emergency Planning and Community Right-to-Know Act of 1986," Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct or accelerator produced material.

(n) The licensee must have and maintain liability coverage for incidents which would activate the plan to cover bodily injury and property damage to third parties caused by incidents which would activate the plan in the amount of at least one million dollars per occurrence with an annual aggregate of at least two million dollars, exclusive of legal defense costs.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident sixty days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the sixty days to the department with the emergency plan.

(H) Information provided by a licensee or applicant for a license or license renewal that constitutes a "trade secret" as defined in section 1333.61 of the Revised Code is not subject to public disclosure in accordance with sections 1333.61 to 1333.69 of the Revised Code.

(I) An application from a medical facility, or educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial

transfer to licensees in its consortium authorized for medical use in accordance with rules in Chapter 58 of the Administrative Code shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with rule 3701:1-38-02 of the Administrative Code for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in paragraph (A)(2) of rule 3701:1-46-43 of the Administrative Code.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in paragraph (B)(2) of rule 3701:1-46-43 of the Administrative Code.

(4) Information identified in paragraph (A)(3) of rule 3701:1-46-43 of the Administrative Code, on the PET drugs to be non-commercially transferred to members of its consortium.

Effective: 10/04/2010

R.C. 119.032 review dates: 06/25/2010 and 06/01/2015

CERTIFIED ELECTRONICALLY

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Certification

09/24/2010

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Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
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Appendix A

Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

Radionuclide[1]	Release Fraction	Quantity (TBq)	Quantity (Ci)
Actinium-228	0.001	148	4,000
Americium-241	0.001	0.074	2
Americium-242	0.001	0.074	2
Americium-243	0.001	0.074	2
Antimony-124	0.01	148	4,000
Antimony-126	0.01	222	6,000
Barium-133	0.01	370	10,000
Barium-140	0.01	1110	30,000
Bismuth-207	0.01	185	5,000
Bismuth-210	0.01	22.2	600
Cadmium-109	0.01	37	1,000
Cadmium-113	0.01	2.96	80
Calcium-45	0.01	740	20,000
Californium-252	0.001	0.333	9 (20 MG)
Carbon-14 (non-carbon dioxide)	0.01	1850	50,000
Cerium-141	0.01	370	10,000
Cerium-144	0.01	11.1	300
Cesium-134	0.01	74	2,000
Cesium-137	0.01	111	3,000
Chlorine-36	0.5	3.7	100
Chromium-51	0.01	11100	300,000
Cobalt-60	0.001	185	5,000
Copper-64	0.01	7400	200,000
Curium-242	0.001	2.22	60

Appendix A

Radionuclide[1]	Release Fraction	Quantity (TBq)	Quantity (Ci)
Curium-243	0.001	0.111	3
Curium-244	0.001	0.148	4
Curium-245	0.001	0.074	2
Europium-152	0.01	18.5	500
Europium-154	0.01	14.8	400
Europium-155	0.01	111	3,000
Germanium-68	0.01	74	2,000
Gadolinium-153	0.01	185	5,000
Gold-198	0.01	1110	30,000
Hafnium-172	0.01	14.8	400
Hafnium-181	0.01	259	7,000
Holmium-166m	0.01	3.7	100
Hydrogen-3	0.5	740	20,000
Iodine-125	0.5	0.37	10
Iodine-131	0.5	0.37	10
Indium-114m	0.01	37	1,000
Iridium-192	0.001	1480	40,000
Iron-55	0.01	1480	40,000
Iron-59	0.01	259	7,000
Krypton-85	1.0	222000	6,000,000
Lead-210	0.01	0.296	8
Manganese-56	0.01	2220	60,000
Mercury-203	0.01	370	10,000
Molybdenum-99	0.01	1110	30,000
Neptunium-237	0.001	0.074	2
Nickel-63	0.01	740	20,000

Appendix A

Radionuclide[1]	Release Fraction	Quantity (TBq)	Quantity (Ci)
Niobium-94	0.01	11.1	300
Phosphorus-32	0.5	3.7	100
Phosphorus-33	0.5	37	1,000
Polonium-210	0.01	0.37	10
Potassium-42	0.01	333	9,000
Promethium-145	0.01	140	4,000
Promethium-147	0.01	148	4,000
Radium-226	0.001	3.7	100
Ruthenium-106	0.01	7.4	200
Samarium-151	0.01	148	4,000
Scandium-46	0.01	111	3,000
Selenium-75	0.01	370	10,000
Silver-110m	0.01	37	1,000
Sodium-22	0.01	333	9,000
Sodium-24	0.01	370	10,000
Strontium-89	0.01	111	3,000
Strontium-90	0.01	3.33	90
Sulfur-35	0.5	33.3	900
Technetium-99	0.01	370	10,000
Technetium-99m	0.01	14800	400,000
Tellurium-127m	0.01	185	5,000
Tellurium-129m	0.01	185	5,000
Terbium-160	0.01	148	4,000
Thulium-170	0.01	148	4,000
Tin-113	0.01	370	10,000
Tin-123	0.01	111	3,000

Appendix A

Radionuclide[1]	Release Fraction	Quantity (TBq)	Quantity (Ci)
Tin-126	0.01	37	1,000
Titanium-44	0.01	3.7	100
Vanadium-48	0.01	259	7,000
Xenon-133	1.0	33300	900,000
Yttrium-91	0.01	74	2,000
Zinc-65	0.01	185	5,000
Zirconium-93	0.01	14.8	400
Zirconium-95	0.01	185	5,000
Any other beta-gamma emitter	0.01	370	10,000
Mixed fission products	0.01	37	1,000
Mixed corrosion products	0.01	370	10,000
Contaminated equipment beta-gamma	0.001	370	10,000
Irradiated material, any form other than solid noncombustible.	0.01	37	1,000
Irradiated material, solid noncombustible	0.001	370	10,000
Mixed radioactive waste, beta-gamma	0.01	37	1,000
Packaged mixed waste, beta-gamma	0.001	370	10,000
Any other alpha emitter	0.001	0.074	2
Contaminated equipment, alpha	0.0001	0.74	20
Packaged waste, alpha	0.0001	0.74	20
Combinations of radioactive materials listed above[1]			

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in this appendix exceeds one.

[2] Waste packaged in Type B containers does not require an emergency plan.

3701:1-40-16 **Terms and conditions of licenses.**

(A) A license, or any right under a license, shall not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the director finds that the transfer is in accordance with this rule and Chapters 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code. A license or any right contained therein may not be transferred or conveyed without the written authorization of the director. If the director approves the transfer and receives payment of the appropriate licensing fee, a new license will be issued to the transferee.

(B) Each licensee shall confine possession and use of radioactive material to the locations and purposes authorized in the license. Preparation for shipment and transport of radioactive material shall be in accordance with Chapter 3701:1-50 of the Administrative Code.

(C) The director may incorporate at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements or conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as the director deems appropriate or necessary in order to protect the environment, protect health, or minimize danger to life or property. The director may require such reports and the keeping of such records, and provide for such inspections of activities under the license as may be necessary to effectuate the purposes of Chapter 3748. of the Revised Code or rules adopted thereunder.

(D) A licensee that is required to submit an emergency plan pursuant to rule 3701:1-40-14 of the Administrative Code shall follow the emergency plan approved by the director. The licensee may amend the approved plan without approval of the director provided that the amendment does not decrease the effectiveness of the plan. Within six months after amending the emergency plan, the licensee shall furnish the amended plan to both the director and to affected offsite response organizations. Any proposed amendment to the emergency plan that decreases, or potentially decreases, the effectiveness of the approved emergency plan may not be implemented without prior approval by the director.

(E) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with rule 3701:1-58-35 –of the Administrative Code. The licensee shall record the results of each test and retain each record for three years after the record is made.

(F) Each licensee must notify the department by certified mail within ten business days of the commencement of a voluntary or involuntary bankruptcy petition that has been filed by or against:

(1) The licensee;

(2) An entity, defined in this rule as person, estate, trust, governmental unit, and United States trustee, controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate of the licensee defined in this rule as an entity that directly or indirectly owns, controls, or holds with power to vote, twenty per cent or more of the outstanding voting securities of the debtor, other than an entity that holds such securities:

(a) In a fiduciary or agency capacity without sole discretionary power to vote such securities; or

(b) Solely to secure a debt, if such entity has not in fact exercised such power to vote.

The notification shall specify the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing petition.

(G) The director may, upon application including adequate documentation by a person or by his own initiative, grant such exemptions from the requirements of this chapter or other chapters of the Administrative Code involving radioactive materials promulgated under Chapter 3748. of the Revised Code that are authorized by law and will not result in undue hazard to life or property and are otherwise in the public interest.

(H) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(I)

(1) Authorization under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable United States federal drug administration, other federal, and state requirements governing radioactive drugs.

(2) Each licensee authorized under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in paragraph (A)(4) of rule 3701:1-46-43 of the Administrative Code for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment

requirements in paragraph (C) of rule 3701:1-46-43 of the Administrative Code.

(3) A licensee that is a pharmacy authorized under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(a) An authorized nuclear pharmacist that meets the requirements in paragraph (B)(2) of rule 3701:1-46-43 of the Administrative Code, or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in rule 3701:1-58-14 of the Administrative Code.

(4) A pharmacy, authorized under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of paragraph (B)(5) of rule 3701:1-46-43 of the Administrative Code.

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APPENDIX

Byproduct or Accelerator-produced Material	Column I Type B		Column II Type C	
	GBq	Ci	GBq	Ci
Antimony-122	37	1	0.37	0.01
Antimony-124	37	1	0.37	0.01
Antimony-125	37	1	0.37	0.01
Arsenic-73	370	10	3.7	0.1
Arsenic-74	37	1	0.37	0.01
Arsenic-76	37	1	0.37	0.01
Arsenic-77	370	10	3.7	0.1
Barium-131	370	10	3.7	0.1
Barium-140	37	1	0.37	0.01
Beryllium-7	370	10	3.7	0.1
Bismuth-210	3.7	0.1	0.037	0.001
Bromine-82	370	10	3.7	0.1
Cadmium-109	37	1	0.37	0.01
Cadmium-115m	37	1	0.37	0.01
Cadmium-115	370	10	3.7	0.1
Calcium-45	37	1	0.37	0.01
Calcium-47	370	10	3.7	0.1
Carbon-14	3700	100	37	1.0
Cerium-141	370	10	3.7	0.1
Cerium-143	370	10	3.7	0.1
Cerium-144	3.7	0.1	0.037	0.001
Cesium-131	3700	100	37	1.0
Cesium-134m	3700	100	37	1.0

Cesium-134	3.7	0.1	0.037	0.001
Cesium-135	37	1	0.37	0.01
Cesium-136	370	10	3.7	0.1
Cesium-137	3.7	0.1	0.037	0.001
Chlorine-36	37	1	0.37	0.01
Chlorine-38	3700	100	37	1.0
Chromium-51	3700	100	37	1.0
Cobalt-57	370	10	3.7	0.1
Cobalt-58m	3700	100	37	1.0
Cobalt-58	37	1	0.37	0.01
Cobalt-60	3.7	0.1	0.037	0.001
Copper-64	370	10	3.7	0.1
Dysprosium-165	3700	100	37	1.0
Dysprosium-166	370	10	3.7	0.1
Erbium-169	370	10	3.7	0.1
Erbium-171	370	10	3.7	0.1
Europium-152 9.2 h	370	10	3.7	0.1
Europium-152 13 y	3.7	0.1	0.037	0.001
Europium-154	3.7	0.1	0.037	0.001
Europium-155	37	1	0.37	0.01
Fluorine-18	3700	100	37	1.0
Gadolinium-153	37	1	0.37	0.01
Gadolinium-159	370	10	3.7	0.1
Gallium-72	370	10	3.7	0.1
Germanium-71	3700	100	37	1.0
Gold-198	370	10	3.7	0.1
Gold-199	370	10	3.7	0.1
Hafnium-181	37	1	0.37	0.01

Holmium-166	370	10	3.7	0.1
Hydrogen-3	3700	100	37	1.0
Indium-113m	3700	100	37	1.0
Indium-114m	37	1	0.37	0.01
Indium-115m	3700	100	37	1.0
Indium-115	37	1	0.37	0.01
Iodine-125	3.7	0.1	0.037	0.001
Iodine-126	3.7	0.1	0.037	0.001
Iodine-129	3.7	0.1	0.37	0.01
Iodine-131	3.7	0.1	0.037	0.001
Iodine-132	370	10	3.7	0.1
Iodine-133	37	1	0.37	0.01
Iodine-134	370	10	3.7	0.1
Iodine-135	37	1	0.37	0.01
Iridium-192	37	1	0.37	0.01
Iridium-194	370	10	3.7	0.1
Iron-55	370	10	3.7	0.1
Iron-59	37	1	0.37	0.01
Krypton-85	3700	100	37	1.0
Krypton-87	370	10	3.7	0.1
Lanthanum-140	37	1	0.37	0.01
Lutetium-177	370	10	3.7	0.1
Manganese-52	37	1	0.37	0.01
Manganese-54	37	1	0.37	0.01
Manganese-56	370	10	3.7	0.1
Mercury-197m	370	10	3.7	0.1
Mercury-197	370	10	3.7	0.1
Mercury-203	37	1	0.37	0.01

Molybdenum-99	370	10	3.7	0.1
Neodymium-147	370	10	3.7	0.1
Neodymium-149	370	10	3.7	0.1
Nickel-59	370	10	3.7	0.1
Nickel-63	37	1	0.37	0.01
Nickel-65	370	10	3.7	0.1
Niobium-93m	37	1	0.37	0.01
Niobium-95	37	1	0.37	0.01
Niobium-97	3700	100	37	1.0
Osmium-185	37	1	0.37	0.01
Osmium-191m	3700	100	37	1.0
Osmium-191	370	10	3.7	0.1
Osmium-193	370	10	3.7	0.1
Palladium-103	370	10	3.7	0.1
Palladium-109	370	10	3.7	0.1
Phosphorus-32	37	1	0.37	0.01
Platinum-191	370	10	3.7	0.1
Platinum-193m	3700	100	37	1.0
Platinum-193	370	10	3.7	0.1
Platinum-197m	3700	100	37	1.0
Platinum-197	370	10	3.7	0.1
Polonium-210	0.37	0.01	0.0037	0.0001
Potassium-42	37	1	0.37	0.01
Praseodymium-142	370	10	3.7	0.1
Praseodymium-143	370	10	3.7	0.1
Promethium-147	37	1	0.37	0.01
Promethium-149	370	10	3.7	0.1
Radium-226	0.37	0.01	0.0037	0.0001

Rhenium-186	370	10	3.7	0.1
Rhenium-188	370	10	3.7	0.1
Rhodium-103m	37000	1,000	370	10.0
Rhodium-105	370	10	3.7	0.1
Rubidium-86	37	1	0.37	0.01
Rubidium-87	37	1	0.37	0.01
Ruthenium-97	3700	100	37	1.0
Ruthenium-103	37	1	0.37	0.01
Ruthenium-105	370	10	3.7	0.1
Ruthenium-106	3.7	0.1	0.037	0.001
Samarium-151	37	1	0.37	0.01
Samarium-153	370	10	3.7	0.1
Scandium-46	37	1	0.37	0.01
Scandium-47	370	10	3.7	0.1
Scandium-48	37	1	0.37	0.01
Selenium-75	37	1	0.37	0.01
Silicon-31	370	10	3.7	0.1
Silver-105	37	1	0.37	0.01
Silver-110M	3.7	0.1	0.037	0.001
Silver-111	370	10	3.7	0.1
Sodium-22	3.7	0.1	0.037	0.001
Sodium-24	37	1	0.37	0.01
Strontium-85m	37000	1,000	370	10.0
Strontium-85	37	1	0.37	0.01
Strontium-89	37	1	0.37	0.01
Strontium-90	0.37	0.01	0.0037	0.0001
Strontium-91	370	10	3.7	0.1
Strontium-92	370	10	37	0.1

Sulphur-35	370	10	3.7	0.1
Tantalum-182	37	1	0.37	0.01
Technetium-96	370	10	3.7	0.1
Technetium-97m	370	10	3.7	0.1
Technetium-97	370	10	3.7	0.1
Technetium-99m	3700	100	37	1.0
Technetium-99	37	1	0.37	0.01
Tellurium-125m	37	1	0.37	0.01
Tellurium-127m	37	1	0.37	0.01
Tellurium-127	370	10	3.7	0.1
Tellurium-129m	37	1	0.37	0.01
Tellurium-129	3700	100	37	1.0
Tellurium-131m	370	10	3.7	0.1
Tellurium-132	37	1	0.37	0.01
Terbium-160	37	1	0.37	0.01
Thallium-200	370	10	3.7	0.1
Thallium-201	370	10	3.7	0.1
Thallium-202	370	10	3.7	0.1
Thallium-204	37	1	0.37	0.01
Thulium-170	37	1	0.37	0.01
Thulium-171	37	1	0.37	0.01
Tin-113	37	1	0.37	0.01
Tin-125	37	1	0.37	0.01
Tungsten-181	37	1	0.37	0.01
Tungsten-185	37	1	0.37	0.01
Tungsten-187	370	10	3.7	0.1
Vanadium-48	37	1	0.37	0.01
Xenon-131m	37000	1,000	370	10.0

Xenon-133	3700	100	37	1.0
Xenon-135	3700	100	37	1.0
Ytterbium-175	370	10	3.7	0.1
Yttrium-90	37	1	0.37	0.01
Yttrium-91	37	1	0.37	0.01
Yttrium-92	370	10	3.7	0.1
Yttrium-93	37	1	0.37	0.01
Zinc-65	37	1	0.37	0.01
Zinc-69m	370	10	3.7	0.1
Zinc-69	3700	100	37	1.0
Zirconium-93	37	1	0.37	0.01
Zirconium-95	37	1	0.37	0.01
Zirconium-97	37	1	0.37	0.01
Any byproduct or accelerator produced material other than alpha emitting byproduct material not listed above.	3.7	0.1	0.037	0.001