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

(A)

(1) 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.

(2) An application for transfer of license must include:

(a) The identity, technical and financial qualifications of the proposed transferee; and

(b) Financial assurance for decommissioning information required by rule 3701:1-40-17 of the Administrative Code.

(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 director 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.

Five Year Review (FYR) Dates: 04/08/2015 and 04/01/2020

CERTIFIED ELECTRONICALLY

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Certification

04/08/2015

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Date

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