3701:1-58-06 **License required.**

(A) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the director, United States nuclear regulatory commission, an agreement state, or as allowed in paragraph (B)(1) or (B)(2) of this rule.

(B) A specific license is not needed for an individual who:

(1) Receives, possesses, uses, or transfers radioactive material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in rule 3701:1-58-14 of the Administrative Code, unless prohibited by license condition; or

(2) Prepares unsealed radioactive material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in rule 3701:1-58-14 of the Administrative Code, unless prohibited by license condition.

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3701:1-58-08 **License amendments.**

A licensee shall apply for and must receive a license amendment and pay the invoiced amendment fee specified in rule 3701:1-38-02 of the Administrative Code:

(A) Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but that is not authorized on the licensee's current license issued under this chapter, and Chapter 3701:1-40 of the Administrative Code;

(B) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except:

(1) For an authorized user, an individual who meets the requirements in rule 3701:1-58-22, and paragraph (A) of rule 3701:1-58-33, paragraph (A) of rule 3701:1-58-36, paragraph (A) of rule 3701:1-58-40, paragraph (A) of rule 3701:1-58-41, paragraph (A) of rule 3701:1-58-42, paragraph (A) of rule 3701:1-58-51, paragraph (A) of rule 3701:1-58-54, and paragraph (A) of rule 3701:1-58-71 of the Administrative Code.

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in paragraph (A) of rule 3701:1-58-20 and rule 3701:1-58-22 of the Administrative Code.

(3) For an authorized medical physicist, an individual who meets the requirements in paragraph (A) of rule 3701:1-58-19 and rule 3701:1-58-22 of the Administrative Code.

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

(a) On a United States nuclear regulatory commission or agreement state license or other equivalent permit or license recognized by the director that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(b) On a permit issued by a United States nuclear regulatory commission~~,~~ or agreement state specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(c) On a permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(d) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;

(C) Before a radiation safety officer is changed, except as provided in rule 3701:1-58-12 of the Administrative Code;

(D) Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(E) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either rule 3701:1-58-32 or 3701:1-58-34 of the Administrative Code;

(F) Before it changes the address(es) of use identified in the application or on the license; and

(G) Before it revises procedures required by rules 3701:1-58-58 and 3701:1-58-64 to 3701:1-58-66 of the Administrative Code, as applicable, where such revision reduces radiation safety.

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3701:1-58-09 **Notifications.**

(A) A licensee shall provide the director a copy of the board certification and the written attestation(s), signed by a preceptor, the United States nuclear regulatory commission or agreement state license, the permit issued by a United States nuclear regulatory commission master material licensee, the permit issued by a United States nuclear regulatory commission or agreement state licensee of broad scope, or the permit issued by a United States nuclear regulatory commission master material license broad scope permittee for each individual no later than thirty days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under paragraph (B) of rule 3701:1-58-08 of the Administrative Code. For individuals permitted to work under paragraph (B)(4) of rule 3701:1-58-08 of the Administrative Code, within the same thirty day time frame, the licensee shall also provide, as appropriate, verification of completion of;

(1) Any additional case experience required in paragraph (B)(1)(b)(vi) of rule 3701:1-58-40 of the Administrative Code for an authorized user under rule 3701:1-58-37 of the Administrative Code;

(2) Any additional training required in paragraph (C) of rule 3701:1-58-71 of the Administrative Code for an authorized user under rule 3701:1-58-55 of the Administrative Code; and

(3) Any additional training required in paragraph (C) of rule 3701:1-58-19 of the Administrative Code for an authorized medical physicist.

(B) A licensee shall notify the director by letter no later than thirty days after:

(1) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits an authorized user or an individual qualified to be a radiation safety officer under rules 3701:1-58-18 and 3701:1-58-22 of the Administrative Code, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with paragraph (C) of rule 3701:1-58-12 of the Administrative Code.

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in paragraph (A) of rule 3701:1-40-16 of the Administrative Code; or

(5) The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either rule 3701:1-58-32 or 3701:1-58-34 of the Administrative Code.

(C) The licensee shall provide the documents required in this rule to the department either electronically or at the appropriate address identified in rule 3701:1-40-04 of the Administrative Code.

Replaces: 3701:1-58-09

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3701:1-58-10 **Exemptions regarding type A specific licenses of broad scope.**

A licensee possessing a type A specific license of broad scope for medical use, issued under rules 3701:1-40-22 and 3701:1-40-23 of the Administrative Code, is exempt from:

(A) The provisions of paragraph (D) of rule 3701:1-58-07 of the Administrative Code regarding the need to file an amendment to the license for medical use of radioactive material, as described in rule 3701:1-58-72 of the Administrative Code~~.~~;

(B) The provisions of paragraph (B) of rule 3701:1-58-08 of the Administrative Code~~.~~;

(C) The provisions of paragraph (E) of rule 3701:1-58-08 of the Administrative Code regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(D) The provisions of paragraph (A) of rule 3701:1-58-09 of the Administrative Code;

(E) The provisions of paragraph (B)(1) of rule 3701:1-58-09 of the Administrative Code for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(F) The provisions of paragraph (B)(5) of rule 3701:1-58-09 of the Administrative Code regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either rule 3701:1-58-32 or 3701:1-58-34 of the Administrative Code; and

(G) The provisions of paragraph (A) of rule 3701:1-58-17 of the Administrative Code.

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3701:1-58-21 **Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.**

(A)

(1) An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a United States nuclear regulatory commission or agreement state license or a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of rule 3701:1-58-18, 3701:1-58-19, or 3701:1-58-20 of the Administrative Code, respectively.

(2) An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on a United Stated nuclear regulatory commission or agreement state license or a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of rule 3701:1-58-18, 3701:1-58-19, or 3701:1-58-20 of the Administrative Code, respectively.

(3) A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission, need not comply with the training requirements of rule 3701:1-58-18, 3701:1-58-19, or 3701:1-58-20 of the Administrative Code, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(B)

(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the United States nuclear regulatory commission or agreement state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training

requirements of rules 3701:1-58-32 to 3701:1-58-71 of the Administrative Code.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the United States nuclear regulatory commission or agreement state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of rules 3701:1-58-32 to 3701:1-58-71 of the Administrative Code.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission, need not comply with the training requirements of rules 3701:1-58-32 to 3701:1-58-71 of the Administrative Code, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(C) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on United States nuclear regulatory commission licenses for the same uses for which these individuals are authorized.

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3701:1-58-25 **Determination of dosages of unsealed radioactive material for medical use.**

(A) A licensee shall determine and record the activity of each dosage before medical use.

(B) For a unit dosage, this determination must be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

(a) A manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission, or agreement state requirements;

(b) An United States nuclear regulatory commission, or agreement state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by United States food and drug administration; or

(c) A PET radioactive drug producer licensed under paragraph (I) of rule 3701:1-40-14 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements.

(C) For other than unit dosages, this determination must be made by:

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(a) A manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or

(b) A PET radioactive drug producer licensed under paragraph (I) of rule 3701:1-40-14 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements.

(D) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty per cent.

(E) A licensee shall retain a record of the dosage determination required by this rule in accordance with rule 3701:1-58-79 of the Administrative Code.

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3701:1-58-32 **Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.**

Except for quantities that require a written directive under paragraph (B) of rule 3701:1-58-15 of the Administrative Code, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

(A) Obtained from:

(1) A manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or

(2) A PET radioactive drug producer licensed in accordance with paragraph (I) of rule 3701:1-40-14 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirement; or

(B) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist; or

(2) A physician who is an authorized user and who meets the requirements specified in rule 3701:1-58-36, or rule 3701:1-58-40 and paragraph (C)(1)(b)(vii) of rule 3701:1-58-36 of the Administrative Code; or

(3) An individual under the supervision, as specified in rule 3701:1-58-14 of the Administrative Code, of the authorized nuclear pharmacist in paragraph (B)(1) of this rule or the physician who is an authorized user in paragraph (B)(2) of this rule; or

(C) Obtained from and prepared by an United States nuclear regulatory commission or agreement state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by United States food and drug administration; or

(D) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by United States food and drug administration.

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3701:1-58-34 **Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required.**

Except for quantities that require a written directive under paragraph (B) of rule 3701:1-58-15 of the Administrative Code, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(A) Obtained from:

(1) A manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or

(2) A PET radioactive drug producer licensed in accordance with paragraph (I) of rule 3701:1-40-14 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirement; or

(B) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in rule 3701:1-58-36 or 3701:1-58-40 and paragraph (C)(1)(b)(vii) of rule 3701:1-58-36 of the Administrative Code; or

(3) An individual under the supervision, as specified in rule 3701:1-58-14 of the Administrative Code, of the authorized nuclear pharmacist in paragraph (B)(1) of this rule or the physician who is an authorized user in paragraph (B)(2) of this rule;

(C) Obtained from and prepared by an United States nuclear regulatory commission or agreement state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug - protocol accepted by United States food and drug administration; or

(D) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by United States food and drug administration.

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3701:1-58-35 **Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

(A) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(B) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (A) of this rule.

(C) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (A) of this rule.

(D) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with rule 3701:1-58-85 of the Administrative Code.

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3701:1-58-37 **Use of unsealed radioactive material for which a written directive is required.**

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(A) Obtained from:

(1) A manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or

(2) A PET radioactive drug producer licensed in accordance with paragraph (I) of rule 3701:1-40-14 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirement; or

(B) Prepared by, excluding production of PET radionuclides:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in rule 3701:1-58-36 or 3701:1-58-40 of the Administrative Code; or

(3) An individual under the supervision, as specified in rule 3701:1-58-14 of the Administrative Code, of the– authorized nuclear pharmacist in paragraph (B)(1) of this rule or the physician who is an authorized user in paragraph (B)(2) of this rule;

(C) Obtained from and prepared by an United States nuclear regulatory commission or agreement state licensee for use in research in accordance with an investigational new drug protocol accepted by United States food and drug administration; or

(D) Prepared by the licensee for use in research in accordance with an investigational new drug protocol accepted by United States food and drug administration.

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3701:1-58-85 **Records of molybdenum-99, strontium-82, and strontium-85 concentrations.**

A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by paragraph (B) of rule 3701:1-58-35 of the Administrative Code for three years. The record must include:

(A) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel (microcuries) of molybdenum-99 per megabecquerel (millicurie) of technetium-99m, the time and date of the measurement, and the name of the individual who made the measurement; or

(B) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel (microcuries) of strontium-82 per megabecquerel (millicurie) of rubidium-82, kilobecquerel (microcuries) of strontium-85 per megabecquerel (millicurie) of rubidium-82, the time and date of the measurement, and the name of the individual who made the measurement.

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