

3701:1-46-43

Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use.

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

- (1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;
- (2) The applicant submits evidence that the applicant is at least one of the following:
 - (a) Registered or licensed with the United States food and drug administration as a drug manufacturer;
 - (b) Registered or licensed with a state agency as a drug manufacturer; or
 - (c) Licensed as a pharmacy by a state board of pharmacy; or
 - (d) Operating as a nuclear pharmacy within a federal medical institution.
- (3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and
- (4) The applicant satisfies the following labeling requirements:
 - (a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than one hundred days, the time may be omitted.
 - (b) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

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

- (1) May prepare radioactive drugs for medical use, as defined in rule 3701:1-38-01 of the Administrative Code, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (B)(2) and (B)(3) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in rule 3701:1-58-14 of the Administrative Code.
- (2) May allow a pharmacist to work as an authorized nuclear pharmacist if:
 - (a) This individual qualifies as an authorized nuclear pharmacist as defined in rule 3701:1-58-01 of the Administrative Code,
 - (b) This individual meets the requirements specified in paragraph (B) of rule 3701:1-58-20 of the Administrative Code and rule 3701:1-58-22 of the Administrative Code and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
 - (c) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (B)(4) of this rule.
- (3) The actions authorized in paragraphs (B)(1) and (B)(2) of this rule are permitted in spite of more restrictive language in license conditions.
- (4) May designate a pharmacist (as defined in rule 3701:1-38-01 of the Administrative Code) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the United States nuclear regulatory commission or an agreement state.
- (5) Shall provide to the director a copy of each individual's:
 - (a)
 - (i) Certification by a specialty board whose certification process has been recognized by the United States nuclear regulatory commission or an agreement state as specified in paragraph (A) of rule 3701:1-58-20 of the Administrative Code with the written attestation signed by a preceptor as required by paragraph (B)(2) of rule 3701:1-58-20 of the Administrative Code; or
 - (ii) The United States nuclear regulatory commission or agreement state license; or
 - (iii) The permit issued by a licensee of broad scope; and
 - (b) State pharmacy licensure or registration, no later than thirty days after the date that the licensee allows, under paragraphs (B)(2)(a) and (B)(2)(c) of this rule, the individual to work as an authorized nuclear pharmacist.
- (C) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the

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

- (1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
 - (2) Check each instrument for constancy and proper operation at the beginning of each day of use.
- (D) Nothing in this rule relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs.

Effective: 12/22/2008

R.C. 119.032 review dates: 9/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
 Statutory Authority: 3748.02, 3748.04
 Rule Amplifies: 3748.04
 Prior Effective Dates: 10/20/2002, 8/15/05, 1/20/08

3701:1-46-44 **Manufacture and distribution of sources or devices containing radioactive material for medical use.**

- (A) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Chapter 3701:1-58 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or agreement state for use as a calibration, transmission, or reference source or for the uses listed in rules 3701:1-58-43, 3701:1-58-53, 3701:1-58-55, and 3701:1-58-72 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or agreement state will be approved if:
- (1) The applicant satisfies the general requirements in rule 3701:1-40-15 of the Administrative Code;
 - (2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (a) The radioactive material contained, its chemical and physical form, and amount;
 - (b) Details of design and construction of the source or device;
 - (c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
 - (d) For devices containing radioactive material, the radiation profile of a prototype device;
 - (e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
 - (f) Procedures and standards for calibrating sources and devices;
 - (g) Legend and methods for labeling sources and devices as to their radioactive content;
 - (h) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;
 - (3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the director has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in rules 3701:1-58-26, 3701:1-58-43, 3701:1-58-53, and 3701:1-58-55 of the Administrative Code, as

appropriate, and to persons who hold an equivalent license issued by the United States nuclear regulatory commission or an agreement state.

(B) The following is applicable:

- (1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he/she shall include in his/her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.
- (2) In determining the acceptable interval for test of leakage of radioactive material, the director will consider information that includes, but is not limited to:
 - (a) Primary containment (source capsule);
 - (b) Protection of primary containment;
 - (c) Method of sealing containment;
 - (d) Containment construction materials;
 - (e) Form of contained radioactive material;
 - (f) Maximum temperature withstood during prototype tests;
 - (g) Maximum pressure withstood during prototype tests;
 - (h) Maximum quantity of contained radioactive material;
 - (i) Radiotoxicity of contained radioactive material;
 - (j) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

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

Definitions.

Terms defined in rule 3701:1-38-01 of the Administrative Code shall have the same meaning when used in this chapter except as set out herein unless otherwise specifically defined elsewhere:

(A) "Authorized medical physicist" means an individual who:

- (1) Meets the requirements in paragraph (A) of rule 3701:1-58-19 and rule 3701:1-58-22 of the Administrative Code; or
- (2) Is identified as an authorized medical physicist or teletherapy physicist on:
 - (a) A specific medical use license issued by the director, United States nuclear regulatory commission, or an agreement state;
 - (b) A medical use permit issued by a United States nuclear regulatory commission master material licensee;
 - (c) A permit issued by a United States nuclear regulatory commission or agreement state broad scope medical use licensee; or
 - (d) A permit issued by a United States nuclear regulatory commission master material license broad scope medical use permittee.

(B) "Authorized nuclear pharmacist" means a pharmacist who:

- (1) Meets the requirements in paragraph (A) of rule 3701:1-58-20 and rule 3701:1-58-22 of the Administrative Code; or
- (2) Is identified as an authorized nuclear pharmacist on:
 - (a) A specific license issued by the director, United States nuclear regulatory commission, or an agreement state that authorizes medical use or the practice of nuclear pharmacy;
 - (b) A permit issued by a United States nuclear regulatory commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - (c) A permit issued by a United States nuclear regulatory commission or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
 - (d) A permit issued by a United States nuclear regulatory commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
- (3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with rule 3701:1-46-43 of the Administrative Code.

(C) "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in rule 3701:1-58-22 of the Administrative Code 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, or paragraph (A) of rule 3701:1-58-71 of the Administrative Code; or

(2) Is identified as an authorized user on:

(a) A license issued by the director, United States nuclear regulatory commission, or an agreement state that authorizes the medical use of radioactive material;

(b) A permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the medical use of radioactive material;

(c) A permit issued by a United States nuclear regulatory commission, or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(d) A permit issued by a United States nuclear regulatory commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

(D) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

(E) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(F) "Client's address" means the area of use or a temporary job site, as defined in this rule, for the purpose of providing mobile medical service in accordance with rule 3701:1-58-31 of the Administrative Code.

(G) "High dose-rate remote afterloader," as used in this chapter, means a brachytherapy device that remotely delivers a dose rate in excess of twelve gray (one thousand two hundred rads) per hour at the point or surface where the dose is prescribed.

(H) "Low dose-rate remote afterloader," as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of less than or equal to two gray (two hundred rads) per hour at the point or surface where the dose is prescribed.

- (I) "Manual brachytherapy," as used in this chapter, means a type of brachytherapy in which the brachytherapy sources, such as seeds or ribbons are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.
- (J) "Medical event" means an event that meets the criteria in paragraph (A) or (B) of rule 3701:1-58-101 of the Administrative Code.
- (K) "Medium dose-rate remote afterloader," as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of greater than two gray (two hundred rads) per hour, but less than or equal to twelve gray (one thousand two hundred rads) per hour at the point or surface where the dose is prescribed.
- (L) "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.
- (M) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.
- (N) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.
- (O) "Personal Representative" means:
- (1) A person who has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, or
 - (2) A parent, guardian, or other person acting in loco parentis who has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care.
- (P) "Preceptor" means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.
- (Q) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:
- (1) In a written directive; or
 - (2) In accordance with the directions of the authorized user for procedures performed pursuant to rules 3701:1-58-32 and 3701:1-58-34 of the Administrative Code.
- (R) "Prescribed dose" means:
- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive;
 - (3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
 - (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.
- (S) "Pulsed dose-rate remote afterloader," as used in this chapter, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:
- (1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
 - (2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.
- (T) "Radiation safety officer," as used in this chapter, means an individual who:
- (1) Meets the requirements in paragraph (A) or (C)(1) of rule 3701:1-58-18 and rule 3701:1-58-22 of the Administrative Code, or
 - (2) Is identified as a radiation safety officer on:
 - (a) A specific medical use license issued by the director, United States nuclear regulatory commission, or an agreement state that authorizes the medical use of radioactive material; or
 - (b) A medical use permit issued by a United States nuclear regulatory commission master material licensee.
- (U) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.
- (V) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
- (W) "Teletherapy," as used in this chapter, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.
- (X) "Teletherapy Physicist" means the individual identified as the teletherapy physicist on a radioactive material license issued by the state of Ohio.
- (Y) "Temporary job site," as used in this chapter, means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

- (Z) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.
- (AA) "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.
- (BB) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
- (CC) "Type of use" means use of radioactive material under rule 3701:1-58-32, 3701:1-58-34, 3701:1-58-37, 3701:1-58-43, 3701:1-58-53, 3701:1-58-55 or 3701:1-58-72 of the Administrative Code.
- (DD) "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.
- (EE) "Written directive," as specified in rule 3701:1-58-15 of the Administrative Code, means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

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.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

08/05/2005

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

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

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-16

Procedures for administrations requiring a written directive.

- (A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
- (1) The patient's or human research subject's identity is verified before each administration; and
 - (2) Each administration is in accordance with the written directive.
- (B) At a minimum, the procedures required by paragraph (A) of this rule must address the following items that are applicable to the licensee's use of radioactive material:
- (1) Verifying the identity of the patient or human research subject;
 - (2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
 - (3) Checking both manual and computer-generated dose calculations; and
 - (4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by rule 3701:1-58-55 or 3701:1-58-72 of the Administrative Code.
- (C) A licensee shall retain a copy of the procedures required under paragraph (A) of this rule in accordance with rule 3701:1-58-76 of the Administrative Code.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-17

Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use:

- (A) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under Chapter 3701:1-40 and rules 3701:1-38-02 and 3701:1-46-44 of the Administrative Code or equivalent requirements of the United States nuclear regulatory commission or an agreement state;
- (B) Sealed sources or devices noncommercially transferred from an individual licensed in accordance with rule 3701:1-58-06 of the Administrative Code or a United States nuclear regulatory commission or agreement state medical use licensee; or
- (C) Teletherapy sources manufactured and distributed in accordance with a license issued under Chapter 3701:1-40 of the Administrative Code or the equivalent requirements of the United States nuclear regulatory commission or an agreement state.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

Training for radiation safety officer.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in rule 3701:1-58-12 of the Administrative Code to be an individual who:

(A) Is certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraphs (D) and (E) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)

- (a) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of twenty college credits in physical science;
- (b) Have five or more years of professional experience in health physics, for which graduate training may be substituted for no more than two years of the required experience, with at least three years in applied health physics; and
- (c) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)

- (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
- (b) Have two years of full-time practical training and/or supervised experience in medical physics:
 - (i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the director, United States nuclear regulatory commission, or an agreement state; or
 - (ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in rule 3701:1-58-36 or rule 3701:1-58-40 of the Administrative Code; and

- (c) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(B) Has achieved the following requirements:

(1) Has completed a structured educational program consisting of both:

- (a) Two hundred hours of classroom and laboratory training in the following areas:

- (i) Radiation physics and instrumentation;

- (ii) Radiation protection;

- (iii) Mathematics pertaining to the use and measurement of radioactivity;

- (iv) Radiation biology; and

- (v) Radiation dosimetry; and

- (b) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a United States nuclear regulatory commission or agreement state license, or permit issued by a United States nuclear regulatory commission master material licensee, that authorizes similar type(s) of use(s) of radioactive material involving the following:

- (i) Shipping, receiving, and performing related radiation surveys;

- (ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

- (iii) Securing and controlling radioactive material;

- (iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

- (v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

- (vi) Using emergency procedures to control radioactive material; and

- (vii) Disposing of radioactive material; or

(C)

- (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state under paragraph (A) of rule 3701:1-58-19 of the Administrative Code and has experience in

radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as radiation safety officer and who meets the requirements in paragraphs (D) and (E) of this rule; or

- (2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and,
- (D) Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in paragraph (E) and in paragraphs (A)(1)(a) and (A)(1)(b) or (A)(2)(a) and (A)(2)(b) or (B)(1) or (C)(1) or (C)(2) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and
- (E) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Replaces: 3701:1-58-18

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

Training for an authorized medical physicist.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require the authorized medical physicist to be an individual who:

- (A) Is certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraphs (B)(2) and (C) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:
- (1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 - (2) Have two years of full-time practical training and/or supervised experience in medical physics:
 - (a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the director, United States nuclear regulatory commission, or an agreement state; or
 - (b) In clinical radiation facilities providing high-energy, external beam therapy with photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services under the direction of physicians who meet the requirements for authorized users in rule 3701:1-58-51 or rule 3701:1-58-71 of the Administrative Code; and
 - (3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or
- (B)
- (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy with photons and electrons with energies greater than or equal to one million electron volts and brachytherapy services and must include:
 - (a) Performing sealed source leak tests and inventories;

- (b) Performing decay corrections;
 - (c) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - (d) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (C) and either paragraphs (A)(1) and (A)(2), or (B)(1) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in rule 3701:1-58-19 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and
- (C) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Replaces: 3701:1-58-19

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
 Statutory Authority: 3748.02, 3748.04
 Rule Amplifies: 3748.04
 Prior Effective Dates: 8/15/2005

Training for an authorized nuclear pharmacist.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(A) Is certified by a specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (B)(2) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Have graduated from a pharmacy program accredited by the "American Council on Pharmaceutical Education" (ACPE) or have passed the "Foreign Pharmacy Graduate Examination Committee" (FPGEC) examination;
- (2) Hold a current, active license to practice pharmacy;
- (3) Provide evidence of having acquired at least four thousand hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than two thousand hours of the required training and experience; and
- (4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(B) Has achieved the following requirements:

- (1) Has completed seven hundred hours in a structured educational program consisting of both:
 - (a) Two hundred hours of classroom and laboratory training in the following areas:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Chemistry of radioactive material for medical use; and
 - (v) Radiation biology; and
 - (b) Supervised practical experience in a nuclear pharmacy involving:

- (i) Shipping, receiving, and performing related radiation surveys;
 - (ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
 - (iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 - (iv) Using administrative controls to avoid medical events in the administration of radioactive material; and
 - (v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- (2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (A)(1), (A)(2), and (A)(3) or (B)(1) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Replaces: 3701:1-58-09

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
 Statutory Authority: 3748.02, 3748.04
 Rule Amplifies: 3748.04
 Prior Effective Dates: 8/15/2005

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) An individual need not comply with the training requirements of rules 3701:1-58-18, 3701:1-58-19, or 3701:1-58-20 of the Administrative Code, respectively if they were identified as a radiation safety officer, a teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, or an authorized nuclear pharmacist on:

- (1) A United States nuclear regulatory commission license, a permit issued by a United States nuclear regulatory commission broad scope licensee, a master material license permit, or by a master material license permittee of broad scope before October 24, 2002;
- (2) A State of Ohio license or a permit issued by a State of Ohio broad scope licensee before August 15, 2005; or
- (3) An agreement state license or a permit issued by an agreement state broad scope licensee before October 24, 2002.

(B) An individual need not comply with the training requirements of rules 3701:1-58-18, 3701:1-58-19, or 3701:1-58-20 of the Administrative Code, respectively if they were identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on:

- (1) A United States nuclear regulatory commission license, a permit issued by a United States nuclear regulatory commission broad scope licensee, a master material license permit, or by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005;
- (2) A State of Ohio license or a permit issued by a State of Ohio broad scope licensee between August 15, 2005, and the effective date of this rule; or
- (3) An agreement state license or a permit issued by an agreement state broad scope licensee between October 24, 2002, and April 29, 2005.

(C) Physicians, dentists, or podiatrists need not comply with the training requirements of rules 3701:1-58-33, 3701:1-58-36, 3701:1-58-40 to 3701:1-58-42, 3701:1-58-51, 3701:1-58-52, 3701:1-58-54, 3701:1-58-71 and 3701:1-58-104 of the Administrative Code if they were identified as authorized users for the medical use of radioactive material on:

- (1) A United States nuclear regulatory commission license, a permit issued by a United States nuclear regulatory commission broad scope licensee, a master material license permit, or by a master material license permittee of broad scope before April 29, 2005, and perform only those medical uses for which they were authorized before April 29, 2005;
- (2) A State of Ohio license or a permit issued by a State of Ohio broad scope licensee before the effective date of this rule, and perform only those

medical uses for which they were authorized before the effective date of this rule; or

- (3) An agreement state license or a permit issued by an agreement state broad scope licensee before April 29, 2005, and perform only those medical uses for which they were authorized before April 29, 2005.

Replaces: 3701:1-58-21

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-22

Recentness of training.

The training and experience specified in rules 3701:1-58-12 to 3701:1-58-21, 3701:1-58-32 to 3701:1-58-71, and 3701:1-58-104 of the Administrative Code must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Replaces: 3701:1-58-22

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-26 **Authorization for calibration, transmission, and reference sources.**

Any person authorized by rule 3701:1-58-06 of the Administrative Code for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

- (A) Sealed sources, not exceeding 1.11 gigabecquerels (thirty millicuries) each, manufactured and distributed by a person licensed under rule 3701:1-46-44 of the Administrative Code or equivalent United States nuclear regulatory commission, or agreement state regulations.
- (B) Sealed sources, not exceeding 1.11 gigabecquerels (thirty millicuries) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under rule 3701:1-46-44 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.
- (C) Any radioactive material with a half-life not longer than one hundred twenty days in individual amounts not to exceed 0.56 gigabecquerels (fifteen millicuries).
- (D) Any radioactive material with a half-life longer than one hundred twenty days in individual amounts not to exceed the smaller of 7.4 megabecquerels (two hundred microcuries) or one thousand times the quantities in appendix A to rule 3701:1-40-17 of the Administrative Code.
- (E) Technetium-99m in amounts as needed.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-30 **Release of individuals containing unsealed radioactive material or implants containing radioactive material.**

- (A) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem).
- (B) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:
- (1) Guidance on the interruption or discontinuation of breast-feeding; and
 - (2) Information on the potential consequences, if any, of failure to follow the guidance.
- (C) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with paragraph (A) of rule 3701:1-58-82 of the Administrative Code.
- (D) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with rule 3701:1-58-82 of the Administrative Code.
- (E) Any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:
- (1) The patient's name;
 - (2) The radionuclide administered and its activity;
 - (3) The facility name which administered the radionuclide;
 - (4) The date of the administration of the radionuclide; and
 - (5) The expiration date of the card.

The card is not applicable to those patients who are institutionalized in facilities such as hospitals, nursing homes, correctional institutions, etc. or to those patients whose radiation levels do not exceed one microsievert per hour (0.1 mrem/hr) at one meter.

Effective:

12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

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 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) 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 (IND) 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 (IND) protocol accepted by United States food and drug administration.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under:	119.03
Statutory Authority:	3748.02, 3748.04
Rule Amplifies:	3748.04
Prior Effective Dates:	8/15/2005

Training for uptake, dilution, and excretion studies.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under rule 3701:1-58-32 of the Administrative Code to be a physician who:

- (A) Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (C)(2) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - (1) Complete sixty hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (C)(1)(a) and (C)(1)(b) of this rule; and
 - (2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
- (B) Is an authorized user under this rule and rule 3701:1-58-36 or 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or
- (C) Has achieved the following requirements:
 - (1) Has completed sixty hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:
 - (a) Classroom and laboratory training in the following areas:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Chemistry of radioactive material for medical use; and
 - (v) Radiation biology; and

- (b) Work experience, under the supervision of an authorized user who meets the requirements in this rule and rule 3701:1-58-36 or 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements, involving:
- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) Administering dosages of radioactive drugs to patients or human research subjects; and
- (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-36, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph (A)(1) or (C)(1) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-32.

Replaces: 3701:1-58-09

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under:	119.03
Statutory Authority:	3748.02, 3748.04
Rule Amplifies:	3748.04
Prior Effective Dates:	8/15/2005

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 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) Prepared by:
 - (1) An authorized nuclear pharmacist;
 - (2) A physician who is an authorized user and who meets the requirements specified in rules 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 (IND) 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 (IND) protocol accepted by United States food and drug administration.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under:	119.03
Statutory Authority:	3748.02, 3748.04
Rule Amplifies:	3748.04
Prior Effective Dates:	8/15/2005

Training for imaging and localization studies.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in rule 3701:1-58-34 of the Administrative Code to be a physician who:

- (A) Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (C)(2) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - (1) Complete seven hundred hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in paragraphs (C)(1)(a) and (C)(1)(b) of this rule; and
 - (2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
- (B) Is an authorized user under rule 3701:1-58-40 of the Administrative Code and meets the requirements in paragraph (C)(1)(b)(vii) of rule 3701:1-58-36 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
- (C)
 - (1) Has completed seven hundred hours of training and experience, including a minimum of eighty hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:
 - (a) Classroom and laboratory training in the following areas:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Chemistry of radioactive material for medical use; and
 - (v) Radiation biology; and

- (b) Work experience, under the supervision of an authorized user, who meets the requirements in this rule, or rule 3701:1-58-40 of the Administrative Code and paragraph (C)(1)(b)(vii) of this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, involving:
- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (v) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
 - (vi) Administering dosages of radioactive drugs to patients or human research subjects; and
 - (vii) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, or 3701:1-58-40 of the Administrative Code and paragraph (C)(1)(b)(vii) of this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph (A)(1) or (C)(1) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rules 3701:1-58-32 and 3701:1-58-34 of the Administrative Code.

Replaces: 3701:1-58-36

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

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 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) 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 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 (IND) 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 (IND) protocol accepted by United States food and drug administration.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04

Rule Amplifies:
Prior Effective Dates:

3748.04
8/15/2005

Training for use of unsealed radioactive material for which a written directive is required.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under rule 3701:1-58-37 of the Administrative Code to be a physician who:

- (A) Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraphs (B)(1)(b)(vi) and (B)(2) of this rule. Specialty boards whose certification processes have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To be recognized, a specialty board shall require all candidates for certification to:
 - (1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include seven hundred hours of training and experience as described in paragraphs (B)(1)(a) through (B)(1)(b)(v) of this rule. Eligible training programs must be approved by the "Residency Review Committee of the Accreditation Council for Graduate Medical Education," the "Royal College of Physicians and Surgeons of Canada," or the "Committee on Post-Graduate Training of the American Osteopathic Association;" and
 - (2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or
- (B)
 - (1) Has completed seven hundred hours of training and experience, including a minimum of two hundred hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:
 - (a) Classroom and laboratory training in the following areas:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Chemistry of radioactive material for medical use; and
 - (v) Radiation biology; and

- (b) Work experience, under the supervision of an authorized user who meets the requirements in this rule, or equivalent United States nuclear regulatory commission or agreement state requirements. A supervising authorized user, who meets the requirements in paragraph (B) of this rule, must also have experience in administering dosages in the same dosage category or categories, such as paragraph (B)(1)(b)(vi) of this rule, as the individual requesting authorized user status. The work experience must involve:
 - (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
 - (a) Oral administration of less than or equal to 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide I-131, for which a written directive is required;
 - (b) Oral administration of greater than 1.22 gigabecquerels, (thirty-three) millicuries of sodium iodide I-131. Experience with at least three cases in this paragraph also satisfies the requirement in paragraph (B)(1)(b)(vi)(a) of this rule;
 - (c) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than one hundred fifty keV, for which a written directive is required; and/or
 - (d) Parenteral administration of any other radionuclide, for which a written directive is required; and
- (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (A)(1) and (B)(1)(b)(vi), or (B)(1) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written

attestation must be signed by a preceptor authorized user who meets the requirements in this rule, or equivalent United States nuclear regulatory commission or agreement state requirements. The preceptor authorized user, who meets the requirements in paragraph (B) of this rule must have experience in administering dosages in the same dosage category or categories, such as paragraph (B)(1)(b)(vi) of this rule, as the individual requesting authorized user status.

Replaces: 3701:1-58-40

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-41

Training for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (thirty-three millicuries).

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (thirty-three millicuries) to be a physician who:

- (A) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (C)(1) and (C)(2) of this section and whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (C)(3) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov; or
- (B) Is an authorized user under rule 3701:1-58-40 of the Administrative Code for uses listed in paragraph (B)(1)(b)(vi)(a) or (B)(1)(b)(vi)(b) of rule 3701:1-58-40 of the Administrative Code, rule 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
- (C) Has achieved the following requirements:
 - (1) Has successfully completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide iodine-131 for procedures requiring a written directive. The training must include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology;
 - (2) Has work experience, under the supervision of an authorized user who meets the requirements in rule 3701:1-58-40, this rule, or rule 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. —A supervising authorized user who meets the requirements in paragraph (B) of rule 3701:1-58-40 of the Administrative Code must have experience in administering dosages as specified in paragraph (B)(1)(b)(vi)(a) or (B)(1)(b)(vi)(b) of rule 3701:1-58-40 of the Administrative Code. The work experience must involve:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (f) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide iodine-131; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (C)(1) and (C)(2) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule or rules 3701:1-58-40, or 3701:1-58-42 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. A preceptor authorized user, who meets the requirement in paragraph (B) of rule 3701:1-58-40 of the Administrative Code, must also have experience in administering dosages as specified in paragraph (B)(1)(b)(vi)(a) or (B)(1)(b)(vi)(b) of rule 3701:1-58-40 of the Administrative Code.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-42

Training for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (thirty-three millicuries).

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user for the oral administration of sodium iodide iodine-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (thirty-three millicuries) to be a physician who:

- (A) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (C)(1) and (C)(2) of this rule, and whose certification has been recognized by the director, United States nuclear regulatory commission, or an agreement state, and who meets the requirements in paragraph (C)(3) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov; or
- (B) Is an authorized user under rule 3701:1-58-40 of the Administrative Code, for uses listed in paragraph (B)(1)(b)(vi)(b) of rule 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
- (C) Has achieved the following requirements:
 - (1) Has successfully completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide iodine-131 for procedures requiring a written directive. The training must include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology;
 - (2) Has work experience, under the supervision of an authorized user who meets the requirements in rule 3701:1-58-40 or this rule of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. A supervising authorized user who meets the requirements in paragraph (B) of rule 3701:1-58-40 of the Administrative Code, must have experience in administering dosages as specified in paragraph (B)(1)(b)(vi)(b) of rule 3701:1-58-40 of the Administrative Code. The work experience must involve:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (f) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide iodine-131; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (C)(1) and (C)(2) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule or rule 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. A preceptor authorized user, who meets the requirements in paragraph (B) of rule 3701:1-58-40 of the Administrative Code, must also have experience in administering dosages as specified in paragraph (B)(1)(b)(vi)(b) of rule 3701:1-58-40 of the Administrative Code.

Replaces: 3701:1-58-42

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
 Statutory Authority: 3748.02, 3748.04
 Rule Amplifies: 3748.04
 Prior Effective Dates: 8/15/2005

Training for the parenteral administration of unsealed radioactive material requiring a written directive.

(A) Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive, to be a physician who:

- (1) Is an authorized user under rule 3701:1-58-40 of the Administrative Code for uses listed in paragraph (B)(1)(b)(vi)(c) or (B)(1)(b)(vi)(d) of rule 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements;
- (2) Is an authorized user under rule 3701:1-58-51 or 3701:1-58-71 of the Administrative code, or equivalent United States nuclear regulatory commission or agreement state requirements and who meets the requirements in paragraph (B) of this rule; or
- (3) Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state under rules 3701:1-58-51 or 3701:1-58-71 of the Administrative Code, and who meets the requirements in paragraph (B) of this rule.

(B) An authorized user satisfying paragraph (A)(2) or (A)(3) of this rule, shall be a physician who:

- (1) Has successfully completed eighty hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than one hundred fifty keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology; and
- (2) Has work experience, under the supervision of an authorized user who meets the requirements in this rule or rule 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in rule 3701:1-58-40 of the Administrative Code must have

experience in administering dosages as specified in paragraphs (B)(1)(b)(vi)(c) and/or (B)(1)(b)(vi)(d) of rule 3701:1-58-40 of the Administrative Code. The work experience must involve:

- (a) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
 - (b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (e) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
 - (f) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (A)(2) or (A)(3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements. A preceptor authorized user, who meets the requirements in rule 3701:1-58-40 of the Administrative Code must have experience in administering dosages as specified in paragraphs (B)(1)(b)(vi)(c) and/or (B)(1)(b)(vi)(d) of rule 3701:1-58-40 of the Administrative Code.

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

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

Training for use of manual brachytherapy sources.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under rule 3701:1-58-43 of the Administrative Code to be a physician who:

- (A) Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state, and who meets the requirements in paragraph (B)(3) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - (1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the "Residency Review Committee of the Accreditation Council for Graduate Medical Education" or the "Royal College of Physicians and Surgeons of Canada" or the "Committee on Post-Graduate Training of the American Osteopathic Association;" and
 - (2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or
- (B) Has achieved the following requirements:
 - (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
 - (a) Two hundred hours of classroom and laboratory training in the following areas:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology; and
 - (b) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent United States nuclear regulatory commission or agreement state requirements at a medical institution, involving:
 - (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (ii) Checking survey meters for proper operation;
 - (iii) Preparing, implanting, and removing brachytherapy sources;
 - (iv) Maintaining running inventories of material on hand;
 - (v) Using administrative controls to prevent a medical event involving the use of radioactive material; and
 - (vi) Using emergency procedures to control radioactive material;
- (2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, as part of a formal training program approved by the "Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education" or the "Royal College of Physicians and Surgeons of Canada" or the "Committee on Postdoctoral Training of the American Osteopathic Association." This experience may be obtained concurrently with the supervised work experience required by paragraph (B)(1)(b) of this rule; and
- (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements in paragraphs (A)(1), or (B)(1) and (B)(2) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under rule 3701:1-58-43 of the Administrative Code.

Replaces: 3701:1-58-51

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04

Rule Amplifies:
Prior Effective Dates:

3748.04
8/15/2005

3701:1-58-52

Training for ophthalmic use of strontium-90.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

- (A) Is an authorized user under rule 3701:1-58-51 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or
- (B) Has achieved the following requirements:
 - (1) Has completed twenty-four hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. -- The training must include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity; and
 - (d) Radiation biology;
 - (2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
 - (a) Examination of each individual to be treated;
 - (b) Calculation of the dose to be administered;
 - (c) Administration of the dose; and
 - (d) Follow up and review of each individual's case history; and
 - (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or rule 3701:1-58-51 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, that the individual has satisfactorily completed the requirements in paragraphs (A) and (B) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-54

Training for use of sealed sources for diagnosis.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under rule 3701:1-58-53 of the Administrative Code to be a physician, dentist, or podiatrist who:

- (A) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (B) and (C) of this rule and whose certification has been recognized by the director, United States nuclear regulatory commission, or an agreement state. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov; or
- (B) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
- (C) Has completed training in the use of the device for the uses requested.

Replaces: 3701:1-58-54

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in rule 3701:1-58-21 of the Administrative Code, the licensee shall require an authorized user of a sealed source for a use authorized under rule 3701:1-58-55 of the Administrative Code to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the director, United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraphs (B)(3) and (C) of this rule. The names of board certifications which have been recognized by the director, United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's web page at www.nrc.gov. To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the "Residency Review Committee of the Accreditation Council for Graduate Medical Education" or the "Royal College of Physicians and Surgeons of Canada" or the "Committee on Post-Graduate Training of the American Osteopathic Association;" and
- (2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(B) Has achieved the following requirements:

(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(a) Two hundred hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(b) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent United States nuclear regulatory commission or agreement state requirements at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

- (ii) Preparing treatment plans and calculating treatment doses and times;
 - (iii) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - (v) Checking and using survey meters; and
 - (vi) Selecting the proper dose and how it is to be administered;
- (2) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, as part of a formal training program approved by the "Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education" or the "Royal College of Physicians and Surgeons of Canada" or the "Committee on Postdoctoral Training of the American Osteopathic Association." This experience may be obtained concurrently with the supervised work experience required by paragraph (B)(1)(b) of this rule; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (A)(1) or (B)(1) and (B)(2), and (C) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, or equivalent United States nuclear regulatory commission or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and
- (C) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Replaces: 3701:1-58-71

Effective: 12/22/2008

R.C. 119.032 review dates: 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-40-17 **Financial assurance and record keeping for decommissioning.**

- (A) Prior to the department issuing a radioactive materials license:
- (1) Each applicant for a specific license or license renewal authorizing the possession and use of unsealed radioactive material of half-life greater than one hundred twenty days and in quantities exceeding ten thousand times the applicable quantities set forth in appendix A to this rule shall submit a decommissioning funding plan as described in paragraph (D) of this rule. The decommissioning funding plan must also be submitted when a combination of radionuclides is involved if R divided by ten thousand is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in appendix A to this rule.
 - (2) Each applicant for a specific license or license renewal authorizing the possession and use of sealed sources or plated foils of half-life greater than one hundred twenty days and in quantities exceeding one trillion times the applicable quantities of appendix A to this rule, shall submit a decommissioning funding plan as described in paragraph (D) of this rule. The decommissioning funding plan must also be submitted when a combination of radionuclides is involved if R divided by one trillion is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in appendix A to this rule.
- (B) Prior to the department issuing a radioactive materials license, each applicant for a specific license or license renewal authorizing possession and use of radioactive material of half-life greater than one hundred twenty days and in quantities specified in paragraph (C) of this rule shall either:
- (1) Submit a decommissioning funding plan as described in paragraph (D) of this rule; or
 - (2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (C) of this rule using one of the methods described in paragraph (E) of this rule. The applicant shall submit to the department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (E) of this rule.
- (C) Prior to the department issuing a radioactive materials license, an applicant providing certification of financial assurance for decommissioning as specified in paragraph (B)(2) of this rule shall provide the certification in a monetary amount based upon the quantity of licensed material specified as follows:
- (1) Greater than one thousand but less than or equal to ten thousand times the applicable quantities of appendix A to this rule in unsealed form. –For a combination of radionuclides, if R , as defined in paragraph (A) of this rule, divided by one thousand is greater than one but R divided by ten thousand is less than or equal to one, the sum of three hundred thousand dollars.

- (2) Greater than ten billion but less than one trillion times the applicable quantities of appendix A to this rule in sealed sources or plated foils. For a combination of radionuclides, if R, as defined in paragraph (A) of this rule, divided by ten billion is greater than one but R divided by one trillion is less than or equal to one, the sum of one hundred fifty thousand dollars.
- (D) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning in accordance with paragraph (E) of this rule, including the means for adjusting cost estimates and associated funding levels at each renewal over the life of the facility. -The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (E) of this rule.
- (E) Financial assurance for decommissioning, either by a decommissioning funding plan or certification of financial assurance, shall be provided by the licensee and approved by the department prior to the issuance of the license and shall be provided by one or more of the following methods:
- (1) Prepayment by depositing into an account segregated from licensee assets and outside the licensee's administrative control, cash or liquid assets such that the amount of funds will be sufficient to pay decommissioning costs. -- Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.
 - (2) Surety, insurance, or other method in accordance with paragraph (F) of this rule, that guarantees that decommissioning costs will be paid. --A surety method may be in the form of a surety bond, letter of credit, or line of credit. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this paragraph or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company.
 - (3) A parent company guarantee of funds for decommissioning costs based on a financial test may be used provided that the parent company meets the requirements specified in appendix B of this rule. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this rule.
 - (4) For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used provided that the guarantee meets the requirements of appendix C to this rule.
 - (5) For commercial companies that do not issue bonds, a guarantee of funds for decommissioning costs may be used provided that the guarantee meets the requirements of appendix D to this rule.
 - (6) For nonprofit colleges, universities, hospitals, or research and development entities, a guarantee of funds for decommissioning costs may be used

provided that the guarantee meets the requirements of appendix E to this rule. -The director may require proof of nonprofit status.

- (7) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. -An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (E)(2) of this rule.
 - (8) In the case of state or local government licensee, a statement of intent containing a cost estimate for decommissioning or an amount specified in paragraphs (C)(1) to (C)(3) of this rule, and indicating that funds for decommissioning will be obtained when necessary. -As used in this rule, "state or local government licensee" does not include government owned or assisted colleges, universities or hospitals.
- (F) Any surety method or insurance used to provide financial assurance for decommissioning shall be in the form of instruments that contain language as provided in appendix F to this rule, and shall contain the following conditions:
- (1) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless ninety days or more prior to the renewal date, the issuer notifies the director, the beneficiary, and the licensee of its intention not to renew. -The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the director within thirty days after receipt of notification of cancellation.
 - (2) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the director. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.
 - (3) The surety method or insurance must remain in effect until the director has terminated the license.
 - (4) The surety company issuing the bond must, at a minimum, be among those listed as acceptable in the most recent version of "Circular 570" of the United States department of the treasury.
- (G) A licensee must notify the department by certified mail within ten business days of the commencement of a voluntary or involuntary bankruptcy proceeding under Title 11 of the United States Code. -A licensee who fulfills the financial assurance requirements by obtaining a trust fund, surety bond, or other

acceptable financial assurance will be deemed to be without the required financial assurance or liability coverage in the event of bankruptcy of the trustee or issuing institution, or a suspension or revocation of the authority of the trustee institution issuing the instrument. –The licensee shall establish other financial assurance within sixty days after such an event.

(H) Financial assurance for decommissioning, either by a decommissioning funding plan or certification of financial assurance, that is provided by a contract of insurance shall not include any arrangement that constitutes self-insurance. –As used in this rule:

- (1) "Insurance" means a contract issued or underwritten by an insurance company, insurance service, or insurance organization which is licensed to engage in the business of insurance in Ohio, that binds the insurer to indemnify another against a specified loss in return for premiums paid.
- (2) "Self insurance" means a contract of insurance issued either by the licensee or by an insurer affiliated with or an affiliate of the licensee.
- (3) "Affiliate of" or "affiliated with" means that the licensee, either directly or indirectly, through one or more intermediaries or subsidiaries, controls, is controlled by, or is under common control with the insurer.
- (4) "Control", including "controlled by", and "under common control with" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, proxy, membership on the board, or otherwise.

(I) Each person licensed under this chapter, and rule 3701:1-38-02 of the Administrative Code as well as chapters containing rules regarding manufacturing and distribution (Chapter 3701:1-46 of the Administrative Code), industrial radiography (Chapter 3701:1-48 of the Administrative Code), well logging Chapter 3701:1-49 of the Administrative Code), irradiators (Chapter 3701:1-52 of the Administrative Code), and medical use Chapter 3701:1-58 of the Administrative Code) promulgated pursuant to Chapter 3748. of the Revised Code shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with paragraph (B) of rule 3701:1-40-20 of the Administrative Code, a licensee shall transfer all records described in this paragraph to the new licensee, which will be responsible for maintaining these records until the license is terminated. –If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. –As used in this rule, "information important to the decommissioning of a facility" includes the following:

- (1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. –These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known

information on identification of involved radionuclides, quantities, forms, and concentrations.

- (2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. –If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
- (3) Except in the case of an area that contains only a sealed source, provided the source has not leaked or no contamination remains after any leak, or in the case of a byproduct or accelerator produced material having only a half-life of less than sixty-five days, a list contained in a single document and updated every two years, of the following:
 - (a) All areas designated and formerly designated restricted areas as defined in rule 3701:1-38-01 of the Administrative Code.
 - (b) All areas outside of restricted areas that require documentation under paragraph (I)(1) of this rule.
 - (c) All areas outside of restricted areas where current and previous wastes have been buried as documented under rule 3701:1-38-20 of the Administrative Code; and
 - (d) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in rule 3701:1-38-22 of the Administrative Code, or apply for approval for disposal under rule 3701:1-38-19 of the Administrative Code.
- (4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

Effective: 12/22/2008

R.C. 119.032 review dates: 09/15/2008 and 12/01/2013

CERTIFIED ELECTRONICALLY

Certification

12/12/2008

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04, 3748.11
Prior Effective Dates: 7/22/2001, 8/15/05, 7/7/08

APPENDIX A

Radionuclide	Kilobecquerel	Microcuries
Americium-241	0.37	0.01
Antimony-122	3700	100
Antimony-124	370	10
Antimony-125	370	10
Arsenic-73	3700	100
Arsenic-74	370	10
Arsenic-76	370	10
Arsenic-77	3700	100
Barium-131	370	10
Barium-133	370	10
Barium-140	370	10
Bismuth-210	37	1
Bromine-82	370	10
Cadmium-109	370	10
Cadmium-115m	370	10
Cadmium-115	3700	100
Calcium-45	370	10
Calcium-47	370	10
Carbon-14	3700	100
Cerium-141	3700	100
Cerium-143	3700	100
Cerium-144	37	1
Cesium-131	37,000	1,000
Cesium-134m	3700	100
Cesium-134	37	1
Cesium-135	370	10
Cesium-136	370	10
Cesium-137	370	10
Chlorine-36	370	10
Chlorine-38	370	10
Chromium-51	37,000	1,000
Cobalt-57	370	10

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Radionuclide	Kilobecquerel	Microcuries
Cobalt-58m	370	10
Cobalt-58	370	10
Cobalt-60	37	1
Copper-64	3700	100
Dysprosium-165	370	10
Dysprosium-166	3700	100
Erbium-169	3700	100
Erbium-171	3700	100
Europium-152 9.2h	3700	100
Europium-152 13 yr	37	1
Europium-154	37	1
Europium-155	370	10
Fluorine-18	37,000	1,000
Gadolinium-153	370	10
Gadolinium-159	3700	100
Gallium-72	370	10
Germanium-71	3700	100
Gold-198	3700	100
Gold-199	3700	100
Hafnium-181	370	10
Holmium-166	3700	100
Hydrogen-3	37,000	1,000
Indium-113m	3700	100
Indium-114m	370	10
Indium-115m	3700	100
Indium-115	370	10
Iodine-125	37	1
Iodine-126	37	1
Iodine-129	3.7	0.1
Iodine-131	37	1
Iodine-132	370	10
Iodine-133	37	1

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Radionuclide	Kilobecquerel	Microcuries
Iodine-134	370	10
Iodine-135	370	10
Iridium-192	370	10
Iridium-194	3700	100
Iron-55	3700	100
Iron-59	370	10
Krypton-85	3700	100
Krypton-87	370	10
Lanthanum-140	370	10
Lutetium-177	3700	100
Manganese-52	370	10
Manganese-54	370	10
Manganese-56	370	10
Mercury-197m	3700	100
Mercury-197	3700	100
Mercury-203	370	10
Molybdenum-99	3700	100
Neodymium-147	3700	100
Neodymium-149	3700	100
Nickel-59	3700	100
Nickel-63	370	10
Nickel-65	3700	100
Niobium-93m	370	10
Niobium-95	370	10
Niobium-97	370	10
Osmium-185	370	10
Osmium-191m	3700	100
Osmium-191	3700	100
Osmium-193	3700	100
Palladium-103	3700	100
Palladium-109	3700	100
Phosphorus-32	370	10

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Radionuclide	Kilobecquerel	Microcuries
Platinum-191	3700	100
Platinum-193m	3700	100
Platinum-193	3700	100
Platinum-197m	3700	100
Platinum-197	3700	100
Plutonium-239	0.37	0.01
Polonium-210	3.7	0.1
Potassium-42	370	10
Praseodymium-142	3700	100
Praseodymium-143	3700	100
Promethium-147	370	10
Promethium-149	370	10
Radium-226	0.37	0.01
Rhenium-186	3700	100
Rhenium-188	3700	100
Rhodium-103m	3700	100
Rhodium-105	3700	100
Rubidium-86	370	10
Rubidium-87	370	10
Ruthenium-97	3700	100
Ruthenium-103	370	10
Ruthenium-105	370	10
Ruthenium-106	37	1
Samarium-151	370	10
Samarium-153	3700	100
Scandium-46	370	10
Scandium-47	3700	100
Scandium-48	370	10
Selenium-75	370	10
Silicon-31	3700	100
Silver-105	370	10
Silver-110m	37	1

APPENDIX A

Radionuclide	Kilobecquerel	Microcuries
Silver-111	3700	100
Sodium-24	370	10
Strontium-85	370	10
Strontium-89	37	1
Strontium-90	4.44	0.12
Strontium-91	370	10
Strontium-92	370	10
Sulphur-35	3700	100
Tantalum-182	370	10
Technetium-96	370	10
Technetium-97m	3700	100
Technetium-97	3700	100
Technetium-99m	3700	100
Technetium-99	370	10
Tellurium-125m	370	10
Tellurium127m	370	10
Tellurium-127	3700	100
Tellurium129m	370	10
Tellurium-129	3700	100
Tellurium-131m	370	10
Tellurium-132	370	10
Terbium-160	370	10
Thallium-200	3700	100
Thallium-201	3700	100
Thallium-202	3700	100
Thallium-204	370	10
Thorium (natural) ¹	3700	100
Thulium-170	370	10
Thulium-171	370	10
Tin-113	370	10
Tin-125	370	10
Tungsten-181	370	10

APPENDIX A

Radionuclide	Kilobecquerel	Microcuries
Tungsten-185	370	10
Tungsten-187	3700	100
Uranium (natural) ²	3700	100
Uranium-233	0.37	0.01
Uranium-234--Uranium-235	0.37	0.01
Vanadium-48	370	10
Xenon-131m	37,000	1,000
Xenon-133	3700	100
Xenon-135	3700	100
Ytterbium-175	3700	100
Yttrium-90	370	10
Yttrium-91	370	10
Yttrium-92	3700	100
Yttrium-93	3700	100
Zinc-65	370	10
Zinc-69m	3700	100
Zinc-69	37,000	1,000
Zirconium-93	370	10
Zirconium-95	370	10
Zirconium-97	370	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.37	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	3.7	0.1

¹Based on alpha disintegration rate of Th-232, Th-230 and their progeny.

²Based on alpha disintegration rate of U-238, U-234, and U-235.

APPENDIX B

Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial test

- (A) To pass the financial test, the parent company must meet the criteria of either paragraph (A)(1) or (A)(2) of this section:
- (1) The parent company must have:
 - (a) Two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and
 - (b) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and
 - (c) Tangible net worth of at least ten million dollars; and
 - (d) Assets located in the United States amounting to at least ninety percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).
 - (2) The parent company must have:
 - (a) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and
 - (b) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and
 - (c) Tangible net worth of at least ten million dollars; and

- (d) Assets located in the United States amounting to at least ninety percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).
- (B) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the director within ninety days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
- (C) (1) After the initial financial test, the parent company must repeat the passage of the test within ninety days after the close of each succeeding fiscal year.
- (2) If the parent company no longer meets the requirements of paragraph (A) of this section, the licensee must send notice to the director of intent to establish alternate financial assurance as specified in the regulations. The notice must be sent by certified mail within ninety days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within one hundred twenty days after the end of such fiscal year.

III. Parent company guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

- (A) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the director. Cancellation may not occur, however, during the one hundred twenty days beginning on the date of receipt of the notice of cancellation by both the licensee and the director as evidenced by the return receipts.
- (B) If the licensee fails to provide alternate financial assurance as specified in the regulations within ninety days after receipt by the licensee and director of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.
- (C) The parent company guarantee and financial test provisions must remain in effect until the director has terminated the license.
- (D) If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the director. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a

APPENDIX C**Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning by companies that issue bonds.****I. Introduction**

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial test

- (A) To pass the financial test, a company must meet all of the following criteria:
- (1) Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).
 - (2) Assets located in the United States amounting to at least ninety percent of total assets or at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).
 - (3) A current rating for its most recent bond issuance of AAA, AA, or a as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.
- (B) To pass the financial test, a company must meet all of the following additional requirements:
- (1) The company must have at least one class of equity securities registered under the federal Securities Exchange Act of 1934.
 - (2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the director within ninety days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
 - (3) After the initial financial test, the company must repeat passage of the test within ninety days after the close of each succeeding fiscal year.
- (C) If the licensee no longer meets the requirements of section II paragraph (A) of this appendix, the licensee must send immediate notice to the director of its intent to establish alternate financial assurance as specified in the rules within one hundred twenty days of such notice.

III. Company self-guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

- (A) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the director. Cancellation may not occur, however, during the one hundred twenty days beginning on the date of receipt of the notice of cancellation by the director, as evidenced by the return receipt.
- (B) The licensee shall provide alternative financial assurance as specified in the rules within ninety days following receipt by the director of a notice of cancellation of the guarantee.
- (C) The guarantee and financial test provisions must remain in effect until the director has terminated the license or until another financial assurance method acceptable to the director has been put in effect by the licensee.
- (D) The licensee will promptly forward to the director and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the securities and exchange commission pursuant to the requirements of section 13 of the federal Securities and Exchange Act of 1934.
- (E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the director within twenty days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of section II paragraph (A) of this appendix.
- (F) The applicant or licensee must provide to the director a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the director, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

APPENDIX D

Criteria relating to use of financial tests and self-guarantee for providing reasonable assurance of funds for decommissioning by commercial companies that have no outstanding rated bonds

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of section II of this appendix. The terms of the self-guarantee are in section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial test

- (A) To pass the financial test a company must meet the following criteria:
- (1) Tangible net worth greater than ten million dollars, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
 - (2) Assets located in the United States amounting to at least ninety percent of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
 - (3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.
- (B) In addition, to pass the financial test, a company must meet all of the following requirements:
- (1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the director within ninety days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
 - (2) After the initial financial test, the company must repeat passage of the test within ninety days after the close of each succeeding fiscal year.
 - (3) If the licensee no longer meets the requirements of section II,

paragraph (A) of this appendix, the licensee must send notice to the director of intent to establish alternative financial assurance as specified in rule 3701:1-40-17 of the Administrative Code. The notice must be sent by certified mail, return receipt requested, within ninety days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within one hundred twenty days after the end of such fiscal year.

III. Company self-guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

- (A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the director. Cancellation may not occur until an alternative financial assurance mechanism is in place.
- (B) The licensee shall provide alternative financial assurance as specified in the regulations within ninety days following receipt by the director of a notice of cancellation of the guarantee.
- (C) The guarantee and financial test provisions must remain in effect until the director has terminated the license or until another financial assurance method acceptable to the director has been put in effect by the licensee.
- (D) The applicant or licensee must provide to the director a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the director, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

APPENDIX E

Criteria relating to use of financial tests and self-guarantee for providing reasonable assurance of funds for decommissioning by nonprofit colleges, universities, hospitals or nonprofit research and development entities.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of section II of this appendix. The terms of the self-guarantee are in section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial test

- (A) For colleges and universities, to pass the financial test a college or university must meet either the criteria in section II, paragraph (A)(1) or the criteria in section II, paragraph (A)(2) of this appendix.
 - (1) For applicants or licensees that issue bonds, a current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.
 - (2) For applicants or licensees that do not issue bonds, endowment consisting of assets located in the United States of at least fifty million dollars, or at least thirty times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.
- (B) For hospitals or nonprofit research and development entities, to pass the financial test a hospital or nonprofit research and development entity must meet either the criteria in section II, paragraph (B)(1) or the criteria in section II, paragraph (B)(2) of this appendix:
 - (1) For applicants or licensees that issue bonds, a current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.
 - (2) For applicants or licensees that do not issue bonds, all the following tests must be met:
 - (a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.
 - (b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

- (c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.
 - (d) Operating revenues must be at least one hundred times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital or nonprofit research and development entity is responsible as a self-guaranteeing licensee.
- (C) In addition, to pass the financial test, a licensee must meet all the following requirements:
- (1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the director within ninety days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.
 - (2) After the initial financial test, the licensee must repeat passage of the test within ninety days after the close of each succeeding fiscal year.
 - (3) If the licensee no longer meets the requirements of section I of this appendix, the licensee must send notice to the director of its intent to establish alternative financial assurance. The notice must be sent by certified mail, return receipt requested, within ninety days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within one hundred twenty days after the end of such fiscal year.

III. Self-guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

- (A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the director. Cancellation may not occur unless an alternative financial assurance mechanism is in place.
- (B) The licensee shall provide alternative financial assurance as specified in the rules within ninety days following receipt by the director of a notice of cancellation of the guarantee.
- (C) The guarantee and financial test provisions must remain in effect until the director has terminated the license or until another financial assurance method acceptable to the director has been put in effect by the licensee.

- (D) The applicant or licensee must provide to the director a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the director, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.
- (E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of Aa" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the director within twenty days after publication of the change by the rating service.