Chapter 3701:1-58 Medical Use of Radioactive Materials

3701:1-58-01 *[Effective until 8/15/2021]* 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 an 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-01 *[Effective 8/15/2021]* Definitions.

The terms used in this chapter have the same meaning as found in rule 3701:1-38-01 of the Administrative Code, unless an alternative definition is provided in this rule or in another rules of this chapter:

(A) "Associate radiation safety officer" means an individual who:

(1) Meets the requirements in rules 3701:1-58-18 and 3701:1-58-22 of the Administrative Code; and

(2) Is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

(a) A specific medical use license issued by the director, the United States nuclear regulatory commission, or an agreement state; or

(b) A medical use permit issued by a United States nuclear regulatory commission master material licensee.

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

(1) Meets the requirements in paragraph (A) of rule 3701:1-58-19 and in 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, the 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.

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

(1) Meets the requirements in paragraph (A) of rule 3701:1-58-20 and in 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, the 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.

(D) "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, the 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.

(E) "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.

(F) "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.

(G) "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.

(H) "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.

(I) "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.

(J) "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.

(K) "Medical event" means an event that meets the criteria in paragraph (A) or (B) of rule 3701:1-58-101 of the Administrative Code.

(L) "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.

(M) "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

(N) "Ophthalmic physicist" means an individual who:

(1) Meets the requirements in paragraph (A)(2) of rule 3701:1-58-49 and in rule 3701:1-58-22 of the Administrative Code; and

(2) Is identified as an ophthalmic physicist on a:

(a) Specific medical use license issued by the director,the United States nuclear regulatory commission, or an agreement state;

(b) Permit issued by a United States nuclear regulatory commission or agreement state broad scope medical use licensee;

(c) Medical use permit issued by a United States nuclear regulatory commission master material licensee; or

(d) Permit issued by a United States nuclear regulatory commission master material licensee broad scope medical use permittee.

(O) "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.

(P) "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.

(Q) "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.

(R) "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, a radiation safety officer, or an associate radiation safety officer.

(S) "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.

(T) "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.

(U) "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.

(V) "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 in 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, the 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.

(W) "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.

(X) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(Y) "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.

(Z) "Teletherapy Physicist" means the individual identified as the teletherapy physicist on a radioactive material license issued by the state of Ohio.

(AA) "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.

(BB) "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.

(CC) "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.

(DD) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(EE) "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.

(FF) "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.

(GG) "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: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008

3701:1-58-02 Purpose and scope.

This chapter contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this chapter are in addition to, and not in substitution for, other rules of the Administrative Code. The requirements and provisions of Chapters 3701:1-38, 3701:1-40, and 3701:1-50 of the Administrative Code also apply to applicants and licensees subject to this chapter unless specifically exempted.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-03 Maintenance of records.

Each record required by this chapter must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-04 Provisions for the protection of human research subjects.

(A) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(B) If the research is conducted, funded, supported, or regulated by a federal agency that has implemented the federal policy for the protection of human subjects as specified in 45 C.F.R. Part 46, as published in the October 1, 2013, Code of Federal Regulations, the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "institutional review board," as defined and described in the federal policy; and

(2) Obtain "informed consent," as defined and described in the federal policy, from the human research subject.

(C) If the research will not be conducted, funded, supported, or regulated by a federal agency that has implemented the federal policy, the licensee shall, before conducting research, apply for and

receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "institutional review board," as defined and described in the federal policy, and approved by the office of human research protection; and

(2) Obtain "informed consent," as defined and described in the federal policy, from the human research subject.

(D) Nothing in this rule relieves licensees from complying with the other requirements in this chapter.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-05 United States food and drug administration, other federal, and state requirements.

Nothing in this chapter relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs or devices.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-06 License required.

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

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

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

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

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 378.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-07 *[Effective until 8/15/2021]* Application for license, amendment or renewal.

(A) An application must be signed by the applicant's or licensee's management as defined in rule 3701:1-38-01 of the Administrative Code.

(B) An application for a license for medical use of radioactive material as described in rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37, 3701:1-58-43, 3701:1-58-53, 3701:1-58-55, and 3701:1-58-72 of the Administrative Code must be made by:

(1) Submitting documentation in accordance with rule 3701:1-40-14 of the Administrative Code, and including the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s);

(2) Submitting the appropriate license fees listed in rule 3701:1-38-02 of the Administrative Code after receiving an invoice from the department; and

(3) Submitting procedures required by rules 3701:1-58-58 and 3701:1-58-64 to 3701:1-58-66 of the Administrative Code, as applicable.

(C) A request for a license amendment or renewal must be made by:

(1) Submitting documentation in accordance with rule 3701:1-40-14 of the Administrative Code;

(2) Submitting the appropriate license or amendment fees listed in rule 3701:1-38-02 of the Administrative Code after receiving an invoice from the department; and

(3) Submitting procedures required by rules 3701:1-58-58 and 3701:1-58-64 to 3701:1-58-66 of the Administrative Code, as applicable.

(D) In addition to the requirements in paragraphs (B) and (C) of this rule, an application for a license or amendment for medical use of radioactive material as described in rule 3701:1-58-72 of the Administrative Code must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in rules 3701:1-58-01 to 3701:1-58-31 of the Administrative Code.

(1) The applicant shall also provide specific information on:

(a) Radiation safety precautions and instructions;

(b) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the director in review of the application.

(E) An applicant that satisfies the requirements specified in rule 3701:1-40-23 of the Administrative Code may apply for a type A specific license of broad scope.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-07 *[Effective 8/15/2021]* Application for license, amendment or renewal.

(A) An application must be signed by the applicant's or licensee's "management", as defined in rule 3701:1-38-01 of the Administrative Code.

(B) An application for a license for medical use of radioactive material, as described in rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37, 3701:1-58-43, 3701:1-58-53, 3701:1-58-55, and 3701:1-58-72 of the Administrative Code, must be made by:

(1) Submitting documentation in accordance with rule 3701:1-40-14 of the Administrative Code, and including the facility diagram; equipment; and training and experience qualifications of the radiation safety officer, associate radiation safety officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s);

(2) Submitting the appropriate license fees listed in rule 3701:1-38-02 of the Administrative Code after receiving an invoice from the department; and

(3) Submitting procedures required by rules 3701:1-58-58 and 3701:1-58-64 to 3701:1-58-66 of the Administrative Code, as applicable.

(C) A request for a license amendment or renewal must be made by:

(1) Submitting documentation in accordance with rule 3701:1-40-14 of the Administrative Code;

(2) Submitting the appropriate license or amendment fees listed in rule 3701:1-38-02 of the Administrative Code after receiving an invoice from the department; and

(3) Submitting procedures required by rules 3701:1-58-58 and 3701:1-58-64 to 3701:1-58-66 of the Administrative Code, as applicable.

(D) In addition to the requirements in paragraphs (B) and (C) of this rule, an application for a license or amendment for medical use of radioactive material as described in rule 3701:1-58-72 of the Administrative Code must also include:

(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, rules 3701:1-58-01 to 3701:1-58-31, 3701:1-58-73 to 3701:1-58-103, and 3701:1-58-105 of the Administrative Code;

(2) Identification of and commitment to follow the applicable radiation safety program requirements in rules 3701:1-58-32 to 3701:1-58-71, 3701:1-58-104 of the Administrative Code that are appropriate for the specific rule 3701:1-58-72 of the Administrative Code medical use;

(3) Any additional specific information on:

(a) Radiation safety precautions and instructions;

(b) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) Any other information requested by the director in review of the application.

(E) An applicant that satisfies the requirements specified in rule 3701:1-40-23 of the Administrative Code may apply for a type A specific license of broad scope.

Replaces: 3701:1-58-07

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 10/04/2010

3701:1-58-08 *[Effective until 8/15/2021]* 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-08 *[Effective 8/15/2021]* 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, ophthalmic physicist, 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, ophthalmic physicist, 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 permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;

(E) 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;

(F) 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;

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

(H) 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; and

(I) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the sealed source and device registry, and is in a quantity and for an isotope authorized by the license.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008

3701:1-58-09 *[Effective until 8/15/2021]* 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 director either electronically or at the appropriate address identified in rule 3701:1-40-04 of the Administrative Code.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 11/14/13

3701:1-58-09 *[Effective 8/15/2021]* 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, ophthalmic physicist, 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, an associate radiation safety officer, ophthalmic physicist, 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;

(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; or

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in paragraph (I) of rule 3701:1-58-08 of the Administrative Code. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

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

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 11/14/2013

3701:1-58-10 *[Effective until 8/15/2021]* Exemptions regarding type A specific licenses of broad scope.

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

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

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

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

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

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

(F) The provisions of paragraph (B)(5) of rule 3701:1-58-09 of the Administrative Code regarding additions to or changes in the areas of use identified in the application or on the license where

radioactive material is used in accordance with either rule 3701:1-58-32 or 3701:1-58-34 of the Administrative Code; and

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

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-10 *[Effective 8/15/2021]* Exemptions regarding type A specific licenses of broad scope.

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

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

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

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

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

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

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

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

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 10/04/2010

3701:1-58-11 License issuance.

(A) The director shall issue a license for the medical use of radioactive material if:

(1) The applicant has filed documentation in accordance with rule 3701:1-58-07 of the Administrative Code;

(2) The applicant has paid any applicable fee as provided in rule 3701:1-38-02 of the Administrative Code;

(3) The director finds the applicant equipped and committed to observe the safety standards established by the director for the protection of the public health and safety; and

(4) The applicant meets the requirements of Chapter 3701:1-40 and rule 3701:1-38-02 of the Administrative Code.

(B) The director shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (A) of this rule; and

(2) Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with rule 3701:1-58-30 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-12 *[Effective until 8/15/2021]* Authority and responsibilities for the radiation protection program.

(A) In addition to the radiation protection program requirements of rule 3701:1-38-11 of the Administrative Code, a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to the director;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under rule 3701:1-58-13 of the Administrative Code.

(B) A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(C) For up to sixty days each year, a licensee may permit 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, as provided in paragraph (G) of this rule, if the licensee takes the actions required in paragraphs (B), (E), (G), and (H) of this rule and notifies the director in accordance with paragraph (B) of rule 3701:1-58-09 of the Administrative Code.

(D) A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with paragraph (C) of this rule, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

(E) A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

(F) Licensees that are authorized for two or more different types of uses of radioactive material under rules 3701:1-58-37 to 3701:1-58-52 of the Administrative Code and rules 3701:1-58-55 to 3701:1-58-71 of the Administrative Code, or two or more types of units under rules 3701:1-58-55 to 3701:1-58-71 of the Administrative Code, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The committee may include other members the licensee considers appropriate.

(G) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(H) A licensee shall retain a record of actions taken under paragraphs (A), (B), and (E) of this rule in accordance with rule 3701:1-58-73 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-12 *[Effective 8/15/2021]* Authority and responsibilities for the radiation protection program.

(A) In addition to the radiation protection program requirements of rule 3701:1-38-11 of the Administrative Code, a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to the director;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under rule 3701:1-58-13 of the Administrative Code.

(B) A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(C) For up to sixty days each year, a licensee may permit 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, as provided in paragraph (G) of this rule, if the licensee takes the actions required in paragraphs (B), (E), (G), and (H) of this rule and notifies the director in accordance with paragraph (B) of rule 3701:1-58-09 of the Administrative Code.

(D) A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with paragraph (C) of this rule, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

(E) A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

(F) Licensees that are authorized for two or more different types of uses of radioactive material under rules 3701:1-58-37 to 3701:1-58-52 of the Administrative Code and rules 3701:1-58-55 to 3701:1-58-71 of the Administrative Code, or two or more types of units under rules 3701:1-58-55 to 3701:1-58-71 of the Administrative Code, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The committee may include other members the licensee considers appropriate.

(G) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(H) A licensee shall retain a record of actions taken under paragraphs (A), (B), and (E) of this rule in accordance with rule 3701:1-58-73 of the Administrative Code.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-13 Radiation protection program changes.

(A) A licensee may revise its radiation protection program without the director's approval if:

(1) The revision does not require a license amendment under rule 3701:1-58-08 of the Administrative Code;

(2) The revision is in compliance with the regulations and the license;

(3) The revision has been reviewed and approved by the radiation safety officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(B) A licensee shall retain a record of each change in accordance with rule 3701:1-58-74 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-14 Supervision.

(A) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by paragraph (B)(1) of rule 3701:1-58-06 of the Administrative Code, shall:

(1) In addition to the requirements in rule 3701:1-38-10 of the Administrative Code, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the

licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of radioactive material.

(B) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by paragraph (B)(2) of rule 3701:1-58-06 of the Administrative Code shall:

(1) In addition to the requirements in rule 3701:1-38-10 of the Administrative Code of this chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(C) A licensee that permits supervised activities under paragraph (A) and (B) of this rule is responsible for the acts and omissions of the supervised individual.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-15 *[Effective until 8/15/2021]* Written directives.

(A) A written directive must be dated and signed by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels(thirty microcuries), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty-eight hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name and the following information:

(1) For any administration of quantities greater than 1.11 megabecquerels(thirty microcuries) of sodium iodide iodine-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide iodine-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(a) Before implantation: treatment site, the radionuclide, and dose; and

(b) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(C) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within forty-eight hours of the oral revision.

(D) The licensee shall retain a copy of the written directive in accordance with rule 3701:1-58-75 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-15 *[Effective 8/15/2021]* Written directives.

(A) A written directive must be dated and signed by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (thirty microcuries), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty-eight hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name and the following information:

(1) For any administration of quantities greater than 1.11 megabecquerels (thirty microcuries) of sodium iodide iodine-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide iodine-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(a) Before implantation: treatment site, the radionuclide, and the total source strength; and

(b) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date when the licensee assessed the patient's implantation; or

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(a) Before implantation: The treatment site, radionuclide, and dose; and

(b) After implantation but before completion of the procedure: The radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and the date when the licensee assessed the patient's implantation.

(C) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within forty-eight hours of the oral revision.

(D) The licensee shall retain a copy of the written directive in accordance with rule 3701:1-58-75 of the Administrative Code.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 10/04/2010

3701:1-58-16 *[Effective until 8/15/2021]* 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-16 *[Effective 8/15/2021]* 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;

(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;

(5) Determining if a medical event, as defined in rule 3701:1-58-101 of the Administrative Code, has occurred; and

(6) Determining, for permanent implant brachytherapy, within sixty calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(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: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008

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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-18 *[Effective until 8/15/2021]* 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 3701:1-58-21,3701:1-58-36 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04

Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-18 *[Effective 8/15/2021]* Training for radiation safety officer and associate 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 or an individual assigned duties and tasks as an associate 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, the United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (D) of this rule. The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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 3701:1-58-21, 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 . An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on a United States nuclear regulatory commission or agreement state license, or permit issued by a United States nuclear regulatory commission master material licensee. The fulltime radiation safety experience must involve 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; and

(2) This individual must obtain a written attestation, signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (B)(1) and (D) of this rule, and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; 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 or an associate radiation safety officer and who meets the requirements in paragraph (D) of this rule; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a United States nuclear regulatory commission or an agreement state license, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or an agreement state licensee of broad scope, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer, and meets the requirements in paragraph (D) of this rule; or

(3) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a United States nuclear regulatory commission master material license. The individual must also meet the requirements in paragraph (D) of this rule.

(D) 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, an associate 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.

Effective:	8/15/2021
Five Year Review (FYR) Dates:	11/13/2020 and 08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.04
Rule Amplifies:	3748.04

Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-19 *[Effective until 8/15/2021]* 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 3701:1-58-21, 3701:1-58-51, or 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 paragraphs (A)(1) and (A)(2), or (B)(1) and (C) 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 or 3701:1-58-21 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-19 *[Effective 8/15/2021]* 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, the United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (C) of this rule. The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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 whose certification process has been recognized under this rule by the director, the 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 3701:1-58-21, 3701:1-58-51, or 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 paragraphs (B)(1) and (C) of this rule, and is able to independently fulfill the radiation safety-related duties 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 or 3701:1-58-21 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.

(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.

Effective:	8/15/2021
Five Year Review (FYR) Dates:	11/13/2020 and 08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.04
Rule Amplifies:	3748.04

Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-20 *[Effective until 8/15/2021]* 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: 3701:1-58-20

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03

Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-20 *[Effective 8/15/2021]* 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 . 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 "Medical Uses Licensee Toolkit" 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 paragraph (B)(1) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008

3701:1-58-21 *[Effective until 8/15/2021]* Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(A)

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

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

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

prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(B)

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

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

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

(C) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on Ohio radioactive material licenses for the same uses for which these individuals are authorized.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 10/4/10, 1/1/12

3701:1-58-21 *[Effective 8/15/2021]* Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(A)

(1) An individual identified as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on a United States nuclear regulatory commission or agreement state license or a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before January 14, 2019 need not comply with the training requirements of rule 3701:1-58-18, 3701:1-58-19, or 3701:1-58-20 of the Administrative Code, respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements in paragraph (D) of rule 3701:1-58-18 of the Administrative Code or paragraph (C) of rule 3701:1-58-19 of the Administrative Code, as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the "American Board of Health Physics" in comprehensive health physics; "American Board of Radiology"; "American Board of Nuclear Medicine"; "American Board of Science" in nuclear medicine; "Board of Pharmaceutical Specialties" in nuclear pharmacy; "American Board of Medical Physics" in radiation oncology physics; "Royal College of Physicians and Surgeons of Canada" in nuclear medicine; "American Osteopathic Board of Radiology"; or "American Osteopathic Board of Nuclear Medicine" on or before October 24, 2005, need not comply with the training requirements of rule 3701:1-58-18 of the Administrative Code to be identified as a radiation safety officer or as an associate radiation safety officer on a United States nuclear regulatory commission or an agreement state license or United States nuclear regulatory commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the "American Board of Radiology" in therapeutic radiological physics, Roentgen ray and gamma ray physics, xray and radium physics, or radiological physics, or certified by the "American Board of Medical Physics" in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in rule 3701:1-58-19 of the Administrative Code, for those materials and uses that these individuals performed on or before October 24, 2005.

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

(B)

(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the United States nuclear regulatory commission or agreement state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee on or before January 14, 2019, who perform only

those medical uses for which they were authorized on or before that date need not comply with the training requirements of rules 3701:1-58-32 to 3701:1-58-71 of the Administrative Code.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the United States nuclear regulatory commission or agreement state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee on or before October 24, 2005, need not comply with the training requirements of rules 3701:1-58-32 to 3701:1-58-71 of the Administrative Code for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(a) For uses authorized under rule 3701:1-58-32 of the Administrative Code or rule 3701:1-58-34 of the Administrative Code, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the "American Board of Nuclear Medicine"; diagnostic radiology by the "American Board of Radiology"; diagnostic radiology or radiology by the "American Osteopathic Board of Radiology"; nuclear medicine by the "Royal College of Physicians and Surgeons of Canada"; or "American Osteopathic Board of Nuclear Medicine" in nuclear medicine;

(b) For uses authorized under rule 3701:1-58-37 of the Administrative Code, a physician who was certified on or before October 24, 2005, by the "American Board of Nuclear Medicine"; the "American Board of Radiology" in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the "Royal College of Physicians and Surgeons of Canada"; or the "American Osteopathic Board of Radiology" after 1984;

(c) For uses authorized under rule 3701:1-58-43 of the Administrative Code or rule 3701:1-58-55 of the Administrative Code, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the "American Board of Radiology"; radiation oncology by the "American Osteopathic Board of Radiology"; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the "Canadian Royal College of Physicians and Surgeons"; and

(d) For uses authorized under rule 3701:1-58-53 of the Administrative Code, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the "American Board of Radiology"; nuclear medicine by the "American Board of Nuclear Medicine"; diagnostic radiology or radiology by the "American Osteopathic Board of Radiology"; or nuclear medicine by the "Royal College of Physicians and Surgeons of Canada".

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

(C) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on Ohio radioactive material licenses for the same uses for which these individuals are authorized.

Replaces: 3701:1-58-21

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 10/04/2010, 01/01/2012

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

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-23 Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material.

(A) For direct measurements performed in accordance with rule 3701:1-58-25 of the Administrative Code, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(B) A licensee shall calibrate the instrumentation required in paragraph (A) of this rule in accordance with nationally recognized standards or the manufacturer's instructions.

(C) A licensee shall retain a record of each instrument calibration required by this rule in accordance with rule 3701:1-58-77 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-24 Calibration of survey instruments.

(A) A licensee shall calibrate the survey instruments used to show compliance with this chapter and Chapter 3701:1-38 of the Administrative Code before first use, annually, and following a repair that affects the calibration. A licensee shall:

(1) Calibrate all scales with readings up to ten millisievert(one thousand millirem) per hour with a radiation source;

(2) Calibrate two separate readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(B) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than twenty per cent .

(C) A licensee shall retain a record of each survey instrument calibration in accordance with rule 3701:1-58-78 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

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

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

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

(1) Direct measurement of radioactivity; or

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

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

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

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

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

(1) Direct measurement of radioactivity;

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

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

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

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

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

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

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-26 *[Effective until 8/15/2021]* 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.

(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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-26 *[Effective 8/15/2021]* Authorization for calibration, transmission, and reference sources.

(A) 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:

(1) 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.

(2) 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.

(3) 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).

(4) 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.

(5) Technetium-99m in amounts as needed.

(B) Radioactive material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in rule 3701:1-38-01 of the Adminstrative Code except in accordance with the requirements in rule 3701:1-58-53 of the Adminstrative Code; or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(C) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (A) through (F) of this rule need not list these sources on a specific medical use license.

Replaces: 3701:1-58-26

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008

3701:1-58-27 Requirements for possession of sealed sources and brachytherapy sources.

(A) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(B) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the director, United States nuclear regulatory commission, or an agreement state .

(C) To satisfy the leak test requirements of this rule, the licensee shall measure the sample so that the leak test can detect the presence of one hundred eighty-five becquerels(0.005 microcurie) of radioactive material in the sample.

(D) A licensee shall retain leak test records in accordance with paragraph (A) of rule 3701:1-58-80 of the Administrative Code.

(E) If the leak test reveals the presence of one hundred eighty-five becquerels(0.005

microcurie or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Chapter 3701:1-38 of the Administrative Code, and

(2) File a report within five days of the leak test in accordance with rule 3701:1-58-103 of the Administrative Code.

(F) A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than thirty days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 3.7 megabecquerels(one hundred microcuries) or less of beta or gamma-emitting material or 0.37 megabecquerel (ten microcuries) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.

(G) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with paragraph (B) of rule 3701:1-58-80 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-28 Labeling of vials and syringes.

Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-29 Surveys of ambient radiation exposure rate.

(A) In addition to the surveys required by Chapter 3701:1-38 of the Administrative Code, a licensee shall survey, with a radiation detection survey instrument at the end of each day of use, the following:

(1) All areas where unsealed radioactive material requiring a written directive was prepared for use or administered. This includes all unsealed radiopharmaceuticals prepared for use or administered under rule 3701:1-58-37 of this chapter.

(2) All areas where unsealed radioactive material not requiring a written directive was routinely prepared for use or routinely administered. This includes all unsealed radiopharmaceuticals prepared for use or administered under rule 3701:1-58-32 or rule 3701:1-58-34 of this chapter.

(B) A licensee does not need to perform the surveys required by paragraph (A) of this rule in an area(s) where patients or human research subjects are confined when they cannot be released under rule 3701:1-58-30 of the Administrative Code.

(C) A licensee shall retain a record of each survey in accordance with rule 3701:1-58-81 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-31 Provision of mobile medical service.

(A) A licensee providing mobile medical service shall:

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Chapter 3701:1-38 of the Administrative Code.

(B) A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

(C) A licensee providing mobile medical services shall retain the letter required in paragraph (A)(1) of this rule and the record of each survey required in paragraph (A)(4) of this rule in accordance with paragraph (A) and (B) of rule 3701:1-58-83 of the Administrative Code, respectively.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
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:

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

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

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

(1) An authorized nuclear pharmacist; or

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

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

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

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

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 10/4/10

3701:1-58-33 *[Effective until 8/15/2021]* 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, rule 3701:1-58-21, 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 3701:1-58-21, 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 of the Administrative Code.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-33 *[Effective 8/15/2021]* 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 . 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 "Medical Uses Licensee Toolkit" 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, rule 3701:1-58-21, 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 that the individual has satisfactorily completed the requirements in paragraph (C)(1) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under rule 3701:1-58-32 of the Administrative Code. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in rule 3701:1-58-21, 3701:1-58-33, 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

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in rule 3701:1-58-21, 3701:1-58-33, 3701:1-58-36, or 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraph (C)(1) of this rule.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04

Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

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

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

(A) Obtained from:

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

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

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

(1) An authorized nuclear pharmacist;

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

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

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

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

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/05, 12/22/08, 10/4/10

3701:1-58-35 *[Effective until 8/15/2021]* Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

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

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

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

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

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

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

Replaces: 3701:1-58-35

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-35 *[Effective 8/15/2021]* Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

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

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

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

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

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

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

(E) The licensee shall report any measurement that exceeds the limits in paragraph (A) of this rule at the time of generator elution, in accordance with rule 3701:1-58-105 of the Administrative Code.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 10/04/2010

3701:1-58-36 *[Effective until 8/15/2021]* 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, rule 3701:1-58-21, 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, 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, rule 3701:1-58-21, 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-36 *[Effective 8/15/2021]* 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 . The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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, rule 3701:1-58-21, 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. An authorized nuclear pharmacist who meets the requirements in rule 3701:1-58-20 or 3701:1-58-21 of the Administrative Code may provide the supervised work experience for paragraph (C)(1)(b)(vii) of this rule. 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 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 attestationthat the individual has satisfactorily completed the requirements in paragraph (C)(1) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under rules 3701:1-58-32 and 3701:1-58-34 of the Administrative Code. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code and paragraph (C)(1)(b)(vii) of this rule, or United States nuclear regulatory commission or agreement state requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code and paragraph (C)(1)(b)(vii) of this rule, or United States nuclear regulatory commission or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraph (C)(1) of this rule.

Effective:	8/15/2021
Five Year Review (FYR) Dates:	11/13/2020 and 08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.04
Rule Amplifies:	3748.04

Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-37 *[Effective until 8/15/2021]* Use of unsealed radioactive material for which a written directive is required.

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

(A) Obtained from:

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

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

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

(1) An authorized nuclear pharmacist;

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

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

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

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

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 10/4/10

3701:1-58-37 *[Effective 8/15/2021]* Use of unsealed radioactive material for which a written directive is required.

A licensee may use any unsealed radioactive material identified in paragraph (B)(1)(b)(vi) of rule 3701:1-58-40 the Administrative Code prepared for medical use and for which a written directive is required that is:

(A) Obtained from:

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

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

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

(1) An authorized nuclear pharmacist;

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

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

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

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

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 10/04/2010

3701:1-58-38 Safety instruction for unsealed radioactive material.

In addition to the requirements of rule 3701:1-38-10 of the Administrative Code,

(A) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under rule 3701:1-58-30 of the Administrative Code. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(a) Routine visitation to hospitalized individuals in accordance with paragraph (A)(1) of rule 3701:1-38-13 of the Administrative Code, and

(b) Visitation authorized in accordance with paragraph (C) of rule 3701:1-38-13 of the Administrative Code;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(B) A licensee shall retain a record of individuals receiving instruction in accordance with rule 3701:1-58-86 of the Administrative Code.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748, .02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-39 Safety precautions for unsealed radioactive material.

(A) For each patient or human research subject who cannot be released under rule 3701:1-58-30 of the Administrative Code, a licensee shall:

(1) Quarter the patient or the human research subject either in:

(a) A private room with a private sanitary facility; or

(b) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under rule 3701:1-58-30 of the Administrative Code;

(2) Visibly post the patient's or the human research subject's room with a "radioactive materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(B) A licensee shall notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-40 *[Effective until 8/15/2021]* 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) to (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 rule 3701:1-58-21 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 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 ruleor rule 3701:1-58-21 of the Administrative Code, 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-40 *[Effective 8/15/2021]* 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 paragraph (B)(1)(b) (vi) of this rule. Specialty boards whose certification processes have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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) to (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 rule 3701:1-58-21 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 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 from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under rule 3701:1-58-72 of the Administrative Code. This work experience must involve 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 radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than one hundred fifty keV, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (B)(1) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under rule 3701:1-58-37 of the Administrative Code for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in rule 3701:1-58-21 of the Administrative Code, rule 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in rule 3701:1-58-21 of the Administrative Code, rule 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on

Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraph (B)(1) of this rule.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-41 *[Effective until 8/15/2021]* 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 rule 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 3701:1-58-21, 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)(a) 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, rule 3701:1-58-21,3701:1-58-40, 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/2012

3701:1-58-41 *[Effective 8/15/2021]* 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 rule and whose certification process has been recognized by the director, the United States nuclear regulatory commission, or an agreement state . The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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 3701:1-58-21, 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)(a) 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 is able to independently fulfill the radiation safety-related duties for oral administration of less than or equal to 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide iodine-131 for medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in rule 3701:1-58-21, 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 and has experience in administering dosages as specified in paragraph (B)(1)(b)(vi)(a) or (B) (1)(b)(vi)(b) of the Administrative Code; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements inrule 3701:1-58-21, 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, has experience in administering dosages as specified in paragraph (B)(1)(b) (vi)(a) or (B)(1)(b)(vi)(b) of the Administrative Code, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraphs (C)(1) and (C)(2) of this rule.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-42 *[Effective until 8/15/2021]* 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 3701:1-58-21, 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, rule 3701:1-58-21, or 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-42 *[Effective 8/15/2021]* 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, the United States nuclear regulatory commission, or an agreement state . The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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 3701:1-58-21, 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 is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (thirty-three millicuries) of sodium iodide I-131 for medical uses authorized under rule 3701:1-58-37 of the Administrative Code. The attestation must be obtained from either:.

(a) A preceptor authorized user who meets the requirements in rule 3701:1-58-21, 3701:1-58-40, or this rule of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, and has experience in administering dosages as specified in paragraph (B)(1)(b)(vii)(b) of rule 3701:1-58-40 of the Administrative Code; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in rule 3701:1-58-21, 3701:1-58-40, or this rule of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, has experience in administering dosages as specified in paragraph (B)(1)(b)(vii)(b) of rule 3701:1-58-40 of the Administrative Code, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraphs (C)(1) and (C)(2) of this rule.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-43 *[Effective until 8/15/2021]* Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of rule 3701:1-58-17 of the Administrative Code are met.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-43 *[Effective 8/15/2021]* Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources:

(A) As approved in the sealed source and device registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the sealed source and device registry, but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry; or

(B) In research to deliver therapeutic doses for medical use in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code are met.

Replaces: 3701:1-58-43

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-44 Surveys after source implant and removal.

(A) The licensee shall make a survey to locate and account for all sources that have not been implanted immediately after implanting sources in a patient or a human research subject.

(B) The licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed immediately after removing the last temporary implant source from a patient or a human research subject.

(C) A licensee shall retain a record of the surveys required by paragraphs (A) and (B) of this rule in accordance with rule 3701:1-58-87 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-45 Brachytherapy sources accountability.

(A) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(B) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(C) A licensee shall maintain a record of the brachytherapy source accountability in accordance with rule 3701:1-58-88 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-46 Safety instruction for manual brachytherapy.

In addition to the requirements of rule 3701:1-38-10 of the Administrative Code:

(A) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under rule 3701:1-58-30 of the Administrative Code. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(a) Routine visitation of hospitalized individuals in accordance with paragraph (A)(1) of rule 3701:1-38-13 of the Administrative Code; and

(b) Visitation authorized in accordance with paragraph (C) of rule 3701:1-38-13 of the Administrative Code; and

(5) Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(B) A licensee shall retain a record of individuals receiving instruction in accordance with rule 3701:1-58-86 of the Administrative Code.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-47 Safety precautions for manual brachytherapy.

(A) For each patient or human research subject who is receiving brachytherapy and cannot be released under rule 3701:1-58-30 of the Administrative Code, a licensee shall:

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "radioactive materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(B) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Dislodged from the patient; or

(2) Lodged within the patient following removal of the source applicators.

(C) A licensee shall notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04

Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-48 Calibration measurements of brachytherapy sources.

(A) Before the first medical use of a brachytherapy source, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of paragraph (A) of rule 3701:1-58-60 of the Administrative Code;

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (A)(1) and (A)(2) of this rule.

(B) Instead of a licensee making its own measurements as required in paragraph (A) of this rule, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the "American Association of Physicists in Medicine" (AAPM) that are made in accordance with paragraph (A) of this rule.

(C) A licensee shall mathematically correct the outputs or activities determined in paragraph (A) of this rule for radioactive decay at intervals consistent with one percent radioactive decay.

(D) A licensee shall retain a record of each calibration in accordance with rule 3701:1-58-89 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-49 *[Effective until 8/15/2021]* Decay of strontium-90 sources for ophthalmic treatments.

(A) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under rule 3701:1-58-48 of the Administrative Code.

(B) A licensee shall retain a record of the activity of each strontium-90 source in accordance with rule 3701:1-58-90 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-49 *[Effective 8/15/2021]* Strontium-90 sources for ophthalmic treatments.

(A) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (B) of this rule are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(a) Is identified as an ophthalmic physicist on a specific medical use license issued by the director, United States nuclear regulatory commission or an agreement state; permit issued by a United States nuclear regulatory commission or an agreement state broad scope medical use licensee; medical use permit issued by a United States nuclear regulatory commission master material licensee; or permit issued by a United States nuclear regulatory commission master material licensee broad scope medical use permittee; and

(b) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) Has documented training in:

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in rule 3701:1-58-48 of the Administrative Code.

(B) The individuals who are identified in paragraph (A) of this rule must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under rule 3701:1-58-48 of the Administrative Code; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (A) of this rule will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(C) Licensees must retain a record of the activity of each strontium-90 source in accordance with rule 3701:1-58-90 of the Administrative Code.

Replaces: 3701:1-58-49

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-50 Therapy-related computer systems for manual brachytherapy.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays; and

(D) The accuracy of the software used to determine sealed source positions from radiographic images.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-51 *[Effective until 8/15/2021]* 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 rule 3701:1-58-21 of the Administrative Code, 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 rule 3701:1-58-21 of the Administrative Code, 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 rule 3701:1-58-21 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 paragraphs (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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-51 *[Effective 8/15/2021]* 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, the United States nuclear regulatory commission, or an agreement state . The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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 PostGraduate 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 rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements at a medical facility authorized to use radioactive materials under rule 3701:1-58-43 of the Administrative Code, 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 rule 3701:1-58-21 of the Administrative Code, 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 (B)(1) and (B)(2) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under rule 3701:1-58-43 of the Administrative Code.The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in this rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in his rule or rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraphs (B)(1) and (B)(2) of this rule.

Effective:	8/15/2021
Five Year Review (FYR) Dates:	11/13/2020 and 08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.04
Rule Amplifies:	3748.04

Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-52 *[Effective until 8/15/2021]* 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, rule 3701:1-58-21, or 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-52 *[Effective 8/15/2021]* 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, rule 3701:1-58-21, or 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 (B)(1) and (B)(2) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Effective:	8/15/2021
Five Year Review (FYR) Dates:	11/13/2020 and 08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.04
Rule Amplifies:	3748.04

Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-53 *[Effective until 8/15/2021]* Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-53 *[Effective 8/15/2021]* Use of sealed sources and medical devices for diagnosis.

(A) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the sealed source and device registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

(B) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the sealed source and device registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

(C) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active investigational device exemption (IDE) application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code are met.

Replaces: 3701:1-58-53

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-54 *[Effective until 8/15/2021]* 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

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08

3701:1-58-54 *[Effective 8/15/2021]* Training for use of sealed sources and medical devices 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 or 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 (C) and (D) 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, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" web page at www.nrc.gov; or

(B) Is an authorized user for uses listed in rule 3701:1-58-34 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements; or

(C) 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

(D) Has completed training in the use of the device for the uses requested.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008

3701:1-58-55 *[Effective until 8/15/2021]* Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code are met.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-55 *[Effective 8/15/2021]* Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(A) A licensee must only use sealed sources:

(1) Approved and as provided for in the sealed source and device registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active investigational device exemption (IDE) application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code are met.

(B) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the sealed source and device registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the sealed source and device registry, but must be used in accordance with radiation safety conditions and limitations described in the sealed source and device registry; or

(2) In research in accordance with an active investigational device exemption (IDE) application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code are met.

Replaces: 3701:1-58-55

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-56 Surveys of patients and human research subjects treated with a remote afterloader unit.

(A) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(B) A licensee shall retain a record of these surveys in accordance with rule 3701:1-58-87 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-57 Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(A) Only a person specifically licensed by the director, the United States nuclear regulatory commission, or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(B) Except for low dose-rate remote afterloader units, only a person specifically licensed by the director, United States nuclear regulatory commission, or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(C) For a low dose-rate remote afterloader unit, only a person specifically licensed by the director, United States nuclear regulatory commission, or an agreement state, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(D) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with rule 3701:1-58-91 of the Administrative Code.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-58 *[Effective until 8/15/2021]* Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(A) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(B) A copy of the procedures required by paragraph (A)(4) of this rule must be physically located at the unit console.

(C) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by paragraph (A)(4) of this rule; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(D) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(1) The procedures identified in paragraph (A)(4) of this rule; and

(2) The operating procedures for the unit.

(E) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A licensee shall retain a record of individuals receiving instruction required by paragraph (D) of this rule, in accordance with rule 3701:1-58-86 of the Administrative Code.

(G) A licensee shall retain a copy of the procedures required by paragraphs (A)(4) and (D)(2) of this rule in accordance with rule 3701:1-58-92 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 3748.02, 3748.04

3701:1-58-58 *[Effective 8/15/2021]* Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(A) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(B) A copy of the procedures required by paragraph (A)(4) of this rule must be physically located at the unit console.

(C) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by paragraph (A)(4) of this rule; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(D) A licensee shall :

(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) Provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(a) The procedures identified in paragraph (A)(4) of this rule; and

(b) The operating procedures for the unit.

(E) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A licensee shall retain a record of individuals receiving instruction required by paragraph (D) of this rule, in accordance with rule 3701:1-58-86 of the Administrative Code.

(G) A licensee shall retain a copy of the procedures required by paragraphs (A)(4) and (D)(2)(b) of this rule in accordance with rule 3701:1-58-92 of the Administrative Code.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-59 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(A) A licensee shall control access to the treatment room by a door at each entrance.

(B) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(C) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(D) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(E) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(F) In addition to the requirements specified in paragraphs (A) to (E) of this rule, a licensee shall:

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require:

(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the radiation safety officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(G) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-60 Dosimetry equipment.

(A) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(1) The system must have been calibrated using a system or source traceable to the "National Institute of Standards and Technology" (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the "American Association of Physicists in Medicine" (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past twenty-four months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two per cent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(B) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (A) of this rule. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (A) of this rule.

(C) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with rule 3701:1-58-93 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/5/10

3701:1-58-61 Full calibration measurements on teletherapy units.

(A) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements, as described in rule 3701:1-58-64 of the Administrative Code, indicate that the output differs by more than five per cent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(B) To satisfy the requirement of paragraph (A) of this rule, full calibration measurements must include determination of:

(1) The output within plus or minus three per cent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(C) A licensee shall use the dosimetry system described in paragraph (A) of rule 3701:1-58-60 of the Administrative Code to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (B)(1) of this rule may be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by paragraph (A) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall mathematically correct the outputs determined in paragraph (B)(1) of this rule for radioactive decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one per cent decay for all other nuclides.

(F) Full calibration measurements required by paragraph (A) of this rule and radioactive decay corrections required by paragraph (E) of this rule must be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with rule 3701:1-58-94 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-62 Full calibration measurements on remote afterloader units.

(A) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

(3) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy-five days; and

(4) At intervals not exceeding one year for low dose-rate remote afterloader units.

(B) To satisfy the requirement of paragraph (A) of this rule, full calibration measurements must include, as applicable, determination of:

(1) The output within five per cent;

(2) Source positioning accuracy to within one millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(C) A licensee shall use the dosimetry system described in paragraph (A) of rule 3701:1-58-60 of the Administrative Code to measure the output.

(D) A licensee shall make full calibration measurements required by paragraph (A) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(E) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (B) of this rule, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (A) to (E) of this rule.

(G) A licensee shall mathematically correct the outputs determined in paragraph (B)(1) of this rule for radioactive decay at intervals consistent with one per cent radioactive decay.

(H) Full calibration measurements required by paragraph (A) of this rule and radioactive decay corrections required by paragraph (G) of this rule must be performed by the authorized medical physicist.

(I) A licensee shall retain a record of each calibration in accordance with rule 3701:1-58-94 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-63 Full calibration measurements on gamma stereotactic radiosurgery units.

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements, as described in rule 3701:1-58-66 of the Administrative Code, indicate that the output differs by more than five per cent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(B) To satisfy the requirement of paragraph (A) of this rule, full calibration measurements must include determination of:

(1) The output within three per cent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(C) A licensee shall use the dosimetry system described in paragraph (A) of rule 3701:1-58-60 of the Administrative Code to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (B)(1) of this rule may be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by paragraph (A) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall mathematically correct the outputs determined in paragraph (B)(1) of this rule at intervals not exceeding one month for cobalt-60 and at intervals consistent with one per cent radioactive decay for all other radionuclides.

(F) Full calibration measurements required by paragraph (A) of this rule and radioactive decay corrections required by paragraph (E) of this rule must be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with rule 3701:1-58-94 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-64 Periodic spot-checks for teletherapy units.

(A) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in paragraph (B) of rule 3701:1-58-60 ; and

(6) The difference between the measurement made in paragraph (A)(5) of this rule and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for radioactive decay).

(B) A licensee shall perform measurements required by paragraph (A) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(D) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(E) If the results of the checks required in paragraph (D) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(F) A licensee shall retain a record of each spot-check required by paragraphs (A) and (D) of this rule, and a copy of the procedures required by paragraph (B), in accordance with rule 3701:1-58-95 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-65 Periodic spot-checks for remote afterloader units.

(A) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) Before the first use on any given day that a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader is in operation;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(B) A licensee shall perform the measurements required by paragraph (A) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(D) To satisfy the requirements of paragraph (A) of this rule, spot-checks must, at a minimum, assure proper operation of:

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(E) If the results of the checks required in paragraph (D) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(F) A licensee shall retain a record of each check required by paragraph (D) of this rule and a copy of the procedures required by paragraph (B) of this rule in accordance with rule 3701:1-58-96 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748, 02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-66 Periodic spot-checks for gamma stereotactic radiosurgery units.

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(B) A licensee shall:

(1) Perform the measurements required by paragraph (A) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(C) To satisfy the requirements of paragraph (A)(1) of this rule, spot-checks must, at a minimum:

(1) Assure proper operation of:

(a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(b) Helmet microswitches;

(c) Emergency timing circuits; and

(d) Stereotactic frames and localizing devices (trunnions).

(2) Determine:

(a) The output for one typical set of operating conditions measured with the dosimetry system described in paragraph (B) of rule 3701:1-58-60 ;

(b) The difference between the measurement made in paragraph (C)(2)(a) of this rule and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for radioactive decay);

(c) Source output against computer calculation;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error; and

(f) Trunnion centricity.

(D) To satisfy the requirements of paragraphs (A)(2) and (A)(3) of this rule, spot-checks must assure proper operation of:

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(E) A licensee shall arrange for the repair of any system identified in paragraph (C) of this rule that is not operating properly as soon as possible.

(F) If the results of the checks required in paragraph (D) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(G) A licensee shall retain a record of each check required by paragraphs (C) and (D) of this rule and a copy of the procedures required by paragraph (B) of this rule in accordance with rule 3701:1-58-97 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-67 Additional technical requirements for mobile remote afterloader units.

(A) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(B) In addition to the periodic spot-checks required by rule 3701:1-58-65 of the Administrative Code, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(C) In addition to the requirements for checks in paragraph (B) of this rule, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(D) If the results of the checks required in paragraph (B) of this rule indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(E) A licensee shall retain a record of each check required by paragraph (B) of this rule in accordance with rule 3701:1-58-98 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-68 Radiation surveys for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(A) In addition to the survey requirement in rule 3701:1-38-14 of the Administrative Code, a person subject to rules 3701:1-58-55 to 3701:1-58-71 of the Administrative Code shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the sealed source and device registry.

(B) The licensee shall make the survey required by paragraph (A) of this rule at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(C) A licensee shall retain a record of the radiation surveys required by paragraph (A) of this rule in accordance with rule 3701:1-58-99 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-69 *[Effective until 8/15/2021]* Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(A) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(B) This inspection and servicing may only be performed by persons specifically licensed to do so by the director, the United States nuclear regulatory commission, or an agreement state.

(C) A licensee shall keep a record of the inspection and servicing in accordance with rule 3701:1-58-100 of the Administrative Code.

Effective: 8/10/2015
Five Year Review (FYR) Dates: 05/26/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-69 *[Effective 8/15/2021]* Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(A) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement , to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

(B) This inspection and servicing may only be performed by persons specifically licensed to do so by the director, the United States nuclear regulatory commission, or an agreement state.

(C) A licensee shall keep a record of the inspection and servicing in accordance with rule 3701:1-58-100 of the Administrative Code.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 10/04/2010, 08/10/2015

3701:1-58-70 Therapy-related computer systems for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine sealed source positions from radiographic images; and

(E) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-71 *[Effective until 8/15/2021]* 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 rule 3701:1-58-21 of the Administrative Code, 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 rule 3701:1-58-21 of the Administrative Code, 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 rule 3701:1-58-21 of the Administrative Code, 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 12/22/08, 1/1/12

3701:1-58-71 *[Effective 8/15/2021]* 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, the United States nuclear regulatory commission, or an agreement state and who meets the requirements in paragraph (C) of this rule. The names of board certifications which have been recognized by the director, the United States nuclear regulatory commission, or an agreement state will be posted on the United States nuclear regulatory commission's "Medical Uses Licensee Toolkit" 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 PostGraduate 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 rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, at a medical facility that is authorized to use radioactive materials in rule 3701:1-58-55 of the Administrative Code, 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 rule 3701:1-58-21 of the Administrative Code, 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 (B)(1), (B)(2), and (C) of this rule, and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this rule, rule 3701:1-58-21 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status,

and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraphs (B)(1) and (B)(2) of this rule.

(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.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005, 12/22/2008, 01/01/2012

3701:1-58-72 Other medical uses of radioactive material or radiation from radioactive material.

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37, 3701:1-58-43, 3701:1-58-53 and 3701:1-58-55 of the Administrative Code if:

(A) The applicant or licensee has submitted the information required by paragraphs (B) to (D) of rule 3701:1-58-07 of the Administrative Code; and

(B) The applicant or licensee has received written approval from the director in a license or license amendment and uses the material in accordance with the regulations and specific conditions the director considers necessary for the medical use of the material.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748 .02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-73 *[Effective until 8/15/2021]* Records of authority and responsibilities for radiation protection programs.

(A) A licensee shall retain a record of actions taken by the licensee's management in accordance with paragraph (A) of rule 3701:1-58-12forfiveyears. The record must include a summary of the actions taken and a signature of licensee management.

(B) The licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer as required by paragraph (E) of rule 3701:1-58-12 of the Administrative Code, and a signed copy of each radiation safety officer's agreement to be responsible for implementing the

radiation safety program, as required by paragraph (B) of rule 3701:1-58-12 of the Administrative Code, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-73 *[Effective 8/15/2021]* Records of authority and responsibilities for radiation protection programs.

(A) A licensee shall retain a record of actions taken by the licensee's management in accordance with paragraph (A) of rule 3701:1-58-12 of the Administrative Code for five years. The record must include a summary of the actions taken and a signature of licensee management.

(B) The licensee shall retain a record of the authority, duties, and responsibilities of the radiation safety officer as required by paragraph (E) of rule 3701:1-58-12 of the Administrative Code, and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by paragraph (B) of rule 3701:1-58-12 of the Administrative Code, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

(C) For each associate radiation safety officer appointed under paragraph (B) of rule 3701:1-58-12 of the Administrative Code, the licensee shall retain, for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-74 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with paragraph (A) of rule 3701:1-58-13 of the Administrative Code for five years. The record must include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04

Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-75 Records of written directives.

For purposes of this Chapter, a licensee shall retain a copy of each written directive as required by rule 3701:1-58-15 of the Administrative Code for three years.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-76 Records for procedures for administrations requiring a written directive.

For purposes of this Chapter, a licensee shall retain a copy of the procedures required by paragraph (A) of rule 3701:1-58-16 of the Administrative Code for the duration of the license.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-77 Records of calibrations of instruments used to measure the activity of unsealed radioactive material.

A licensee shall maintain a record of instrument calibrations required by rule 3701:1-58-23 of the Administrative Code for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-78 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by rule 3701:1-58-24 of the Administrative Code for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-79 Records of dosages of unsealed radioactive material for medical use.

(A) For purposes of this chapter, a licensee shall maintain a record of dosage determinations required by rule 3701:1-58-25 of the Administrative Code for three years.

(B) The record must contain:

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 megabecquerels(thirty microcuries);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-80 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(A) A licensee shall retain records of leak tests required by paragraph (B) of rule 3701:1-58-27 of the Administrative Code for three years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(B) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by paragraph (G) of rule 3701:1-58-27 of the Administrative Code for three years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-81 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by rule 3701:1-58-29 of the Administrative Code for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-82 Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

(A) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with rule 3701:1-58-30 of the Administrative Code, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at one meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(B) A licensee shall retain a record that the instructions required by paragraph (B) of rule 3701:1-58-30 of the Administrative Code were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding five millisieverts(0.5 rem).

(C) For purposes of this chapter, the records required by paragraphs (A) and (B) of this rule must be retained for three years after the date of release of the individual.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-83 Records of mobile medical services.

(A) A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by paragraph (A)(1) of rule 3701:1-58-31 of the Administrative Code. Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service.

(B) A licensee shall retain the record of each survey required by paragraph (A)(4) of rule 3701:1-58-31 of the Administrative Code for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-84 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by rule 3701:1-38-19 of the Administrative Code, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

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

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

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

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

Replaces: 3701:1-58-85

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-86 *[Effective until 8/15/2021]* Records of safety instruction.

A licensee shall maintain a record of safety instructions required by rules 3701:1-58-38, 3701:1-58-46, and 3701:1-58-58 of the Administrative Code for three years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-86 *[Effective 8/15/2021]* Records of safety instruction.

A licensee shall maintain a record of safety instructions required by rules 3701:1-58-38, 3701:1-58-46 of the Administrative Code, and the operational and safety instructions required by rule 3701:1-58-58 of the Administrative Code, for three years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-87 Records of surveys after source implant and removal.

For purposes of this Chapter, a licensee shall maintain a record of the surveys required by rules 3701:1-58-44 and 3701:1-58-56 of the Administrative Code for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-88 Records of brachytherapy source accountability.

(A) A licensee shall maintain a record of brachytherapy source accountability required by rule 3701:1-58-45 of the Administrative Code for three years.

(B) For temporary implants, the record must include:

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(C) For permanent implants, the record must include:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-89 Records of calibration measurements of brachytherapy sources.

(A) A licensee shall maintain a record of the calibrations of brachytherapy sources required by rule 3701:1-58-48 of the Administrative Code for three years after the last use of the source.

(B) The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-90 Records of decay of strontium-90 sources for ophthalmic treatments.

(A) A licensee shall maintain a record of the activity of a strontium-90 source required by rule 3701:1-58-49 of the Administrative Code for the life of the source.

(B) The record must include:

(1) The date and initial activity of the source as determined under rule 3701:1-58-48 of the Administrative Code; and

(2) For each decay calculation, the date and the source activity as determined under rule 3701:1-58-49 of the Administrative Code.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-91 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by rule 3701:1-58-57 of the Administrative Code for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-92 Records of safety procedures for remote afterloaders, teletherapy units, or gamma stereotactic radiosurgery units.

A licensee shall retain a copy of the procedures required by paragraphs (A)(4) and (D)(2) of rule 3701:1-58-58 of the Administrative Code until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-93 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(A) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with rule 3701:1-58-60 of the Administrative Code for the duration of the license.

(B) For each calibration, intercomparison, or comparison, the record must include:

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (A) and (B) of rule 3701:1-58-60 of the Administrative Code;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-94 Records of full calibrations for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

(A) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by rules 3701:1-58-61 to 3701:1-58-63 of the Administrative Code for three years.

(B) The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-95 Records of periodic spot-checks for teletherapy units.

(A) A licensee shall retain a record of each periodic spot-check for teletherapy units required by rule 3701:1-58-64 of the Administrative Code for three years.

(B) The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(C) A licensee shall retain a copy of the procedures required by paragraph (B) of rule 3701:1-58-64 of the Administrative Code until the licensee no longer possesses the teletherapy unit.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02. 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-96 Records of periodic spot-checks for remote afterloader units.

(A) A licensee shall retain a record of each spot-check for remote afterloader units required by rule 3701:1-58-65 of the Administrative Code for three years.

(B) The record must include, as applicable:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(C) A licensee shall retain a copy of the procedures required by paragraph (B) of rule 3701:1-58-65 of the Administrative Code until the licensee no longer possesses the remote afterloader unit.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-97 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(A) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by rule 3701:1-58-66 of the Administrative Code for three years.

(B) The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(C) A licensee shall retain a copy of the procedures required by paragraph (B) of rule 3701:1-58-66 of the Administrative Code until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-98 Records of additional technical requirements for mobile remote afterloader units.

(A) A licensee shall retain a record of each check for mobile remote afterloader units required by rule 3701:1-58-67 of the Administrative Code for three years.

(B) The record must include:

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-99 Records of surveys of therapeutic treatment units.

(A) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with rule 3701:1-58-68 of the Administrative Code for the duration of use of the unit.

(B) The record must include:

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-100 *[Effective until 8/15/2021]* Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(A) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by rule 3701:1-58-69 of the Administrative Code for the duration of use of the unit.

(B) The record must contain:

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005

3701:1-58-100 *[Effective 8/15/2021]* Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(A) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by rule 3701:1-58-69 of the Administrative Code for the duration of use of the unit.

(B) The record must contain:

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and the serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Effective: 8/15/2021
Five Year Review (FYR) Dates: 11/13/2020 and 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 08/15/2005

3701:1-58-101 *[Effective until 8/15/2021]* Report and notification of a medical event.

(A) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 sievert(five rem) effective dose equivalent, 0.5 sievert(fifty rem) to an organ or tissue, or 0.5 sievert(fifty rem) shallow dose equivalent to the skin; and

(a) The total dose delivered differs from the prescribed dose by twenty per cent or more;

(b) The total dosage delivered differs from the prescribed dosage by twenty per cent or more or falls outside the prescribed dosage range; or

(c) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty per cent or more.

(2) A dose that exceeds 0.05 sievert(five rem) effective dose equivalent, 0.5 sievert(fifty rem) to an organ or tissue, or 0.5 sievert(fifty rem) shallow dose equivalent to the skin from any of the following:

(a) An administration of a wrong radioactive drug containing radioactive material;

(b) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(c) An administration of a dose or dosage to the wrong individual or human research subject;

(d) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(e) A leaking sealed source; or

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 sievert(fifty rem) to an organ or tissue and fifty per cent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(B) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(C) The licensee shall notify by telephone the Ohio department of health, bureau of radiation protection no later than the next calendar day after discovery of the medical event.

(D) The licensee shall submit a written report to the Ohio department of health, bureau of radiation protection to the address listed in listed in rule 3701:1-40-04 of the Administrative Code within fifteen days after discovery of the medical event.

(1) The written report must include:

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the individual(s) who received the administration;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the individual (or the individual's personal representative), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(E) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful to the individual. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's personal representative. If a verbal notification is made, the licensee shall inform the individual, or appropriate personal representative, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(F) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's personal representative.

(G) A licensee shall:

(1) Annotate a copy of the report provided to the Ohio department of health, bureau of radiation protection with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-101 *[Effective 8/15/2021]* Report and notification of a medical event.

(A) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:

(1) The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

(a) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 sievert (five rem) effective dose equivalent, 0.5 sievert (fifty rem) to an organ or tissue, or 0.5 sievert (fifty rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by twenty per cent or more;

(ii) The total dosage delivered differs from the prescribed dosage by twenty per cent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose for a single fraction, by fifty per cent or more.

(b) A dose that exceeds 0.05 sievert (five rem) effective dose equivalent, 0.5 sievert (fifty rem) to an organ or tissue, or 0.5 sievert (fifty rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(i) 0.5 sievert (fifty rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) Fifty per cent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(2) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(a) The total source strength administered differing by twenty per cent or more from the total source strength documented in the post-implantation portion of the written directive;

(b) The total source strength administered outside of the treatment site exceeding twenty per cent of the total source strength documented in the post-implantation portion of the written directive; or

(c) An administration that includes any of the following:

(i) The wrong radionuclide;

(ii) The wrong individual or human research subject;

(iii) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(iv) A leaking sealed source resulting in a dose that exceeds 0.5 sievert (fifty rem) to an organ or tissue.

(B) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(C) The licensee shall notify by telephone the Ohio department of health, bureau of environmental health and radiation protection no later than the next calendar day after discovery of the medical event.

(D) The licensee shall submit a written report to the Ohio department of health, bureau of environmental health and radiation protection to the address listed in listed in rule 3701:1-40-04 of the Administrative Code within fifteen days after discovery of the medical event.

(1) The written report must include:

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the individual(s) who received the administration;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the individual (or the individual's personal representative), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(E) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful to the individual. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's personal representative. If a verbal notification is

made, the licensee shall inform the individual, or appropriate personal representative, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(F) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's personal representative.

(G) A licensee shall:

(1) Annotate a copy of the report provided to the Ohio department of health, bureau of environmental health and radiation protection with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

Replaces: 3701:1-58-101

Effective:	8/15/2021
Five Year Review (FYR) Dates:	08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.02, 3748.04
Rule Amplifies:	3748.04

Prior Effective Dates: 08/15/2005, 10/04/2010

3701:1-58-102 Report and notification of a dose to an embryo/fetus or a nursing child.

(A) A licensee shall report any dose to an embryo/fetus that is greater than fifty millisievert(five rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(B) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(1) Is greater than fifty millisievert(five rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(C) The licensee shall notify by telephone the Ohio department of health, bureau of radiation protection no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraph (A) or (B) in this rule.

(D) The licensee shall submit a written report to the appropriate address listed in rule 3701:1-40-04 of the Administrative Code within fifteen days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraph (A) or (B) in this rule.

(1) The written report must include:

(a) The licensee's name;

(b) The name of the prescribing physician;

(c) A brief description of the event;

(d) Why the event occurred;

(e) The effect, if any, on the embryo/fetus or the nursing child;

(f) What actions, if any, have been taken or are planned to prevent recurrence; and

(g) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's personal representative), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(E) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty-four hours after discovery of an event that would require reporting under paragraph (A) or (B) of this rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful to the mother. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty-four hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's personal representative instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's personal representative, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(F) A licensee shall:

(1) Annotate a copy of the report provided to the director with the:

(a) Name of the pregnant individual or the nursing child who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-103 Report of a leaking source.

A licensee shall file a report within five days if a leak test required by rule 3701:1-58-27 of the Administrative Code reveals the presence of one hundred eighty-five becquerels(0.005microcurie) or more of removable contamination. The report must be filed with the address listed in rule 3701:1-40-04 of the Administrative Code. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020
Promulgated Under: 119.03
Statutory Authority: 3743.02, 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 8/15/2005, 10/4/10

3701:1-58-104 *[Effective until 8/15/2021]* 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 rule 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, rule 3701:1-58-21, or 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 one hundred fifty 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 one hundred fifty 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 3701:1-58-21, or 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.

Five Year Review (FYR) Dates: 03/09/2017 and 03/01/2022
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 12/22/2008, 1/1/12

3701:1-58-104 *[Effective 8/15/2021]* 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) of rule 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or

(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, the United States nuclear regulatory commission, or an agreement state under rule 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) The physician:

(1) Has successfully completed eighty hours of classroom and laboratory training, applicable to parenteral administrations listed in paragraph (B)(1)(b)(vi)(c) of rule 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements. 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, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, in the parenteral administrations listed in paragraph (B)(1)(b)(vi)(c) of rule 3701:1-58-40 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements. A supervising authorized user who meets the requirements in rule 3701:1-58-40 of the Administrative Code, this rule, or equivalent United States nuclear regulatory commission or agreement state requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. 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, as specified in paragraph (B)(1)(b)(vi)(c) of rule 3701:1-58-40 of the Administrative Code; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (B)(1) and (B)(2) of this rule, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in this rule, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this rule, rule 3701:1-58-21, or 3701:1-58-40 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program 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 "Council on Postdoctoral Training of the American Osteopathic Association", and must include training and experience specified in paragraphs (B)(1) and (B)(2) of this rule.

Replaces: 3701:1-58-104

Effective: 8/15/2021
Five Year Review (FYR) Dates: 08/15/2026
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.04
Prior Effective Dates: 12/22/2008, 01/01/2012

3701:1-58-105 *[Effective 8/15/2021]* Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(A) The licensee shall notify by telephone the department at 614-644-2727 and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in paragraph (A) of rule 3701:1-58-35 of the Administrative Code at the time of generator elution. The telephone report to the department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(B) By an appropriate method listed in rule 3701:1-40-04 of the Administrative Code, the licensee shall submit a written report to the department within thirty calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (A) of this rule.

Effective:	8/15/2021
Five Year Review (FYR) Dates:	08/15/2026
Promulgated Under:	119.03
Statutory Authority:	3748.02, 3748.04
Rule Amplifies:	3748.04

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