DRAFT C 05/13/2022

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS

6 CCR 1007-1 Part 07

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health ~~June 17, 2020~~October 19, 2022, effective date ~~August 14, 2020~~December 15, 2022.

PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS

USE OF RADIONUCLIDES IN THE HEALING ARTS

Section A – General Information

7.1 Purpose and scope.

7.1.1 Authority

Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

7.1.2 Basis and Purpose.

A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

7.1.3 Scope.

This part establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations.

7.1.4 Applicability.

The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

7.1.5 Published material incorporated by reference.

7.1.5.1 Throughout this Part 7, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as

Commented [JSJ1]:
Editorial note 1: All comments (such as this one) shown in the right side margin of this draft document are for information purposes only to assist the reader in understanding the proposed rule change during the review and comment process.
These side margin notes are **not** part of the rule and all comments will be deleted prior to publication of the final rule by the Colorado Secretary of State.

Editorial note 2: Alignment and formatting corrections and minor typographical adjustments may be made in the rule and may not be specifically identified with a side margin comment.

Editorial note 3: The acronym "RATS 2021-1" referenced in the side margin comments of this draft refers to the U.S. Nuclear Regulatory Commission (NRC) regulatory action tracking system (RATS). This system and documents are used to identify and summarize changes to federal regulations that may be required for adoption by an NRC agreement state. To maintain agreement state status, and be consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the NRC.

Colorado statute also prescribes that the radiation control regulations must be consistent with the model regulations of the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD model regulation equivalent to part 7 was last updated in 2003, and does not yet reflect federal rule changes since that time.

Editorial note 4: This is not a complete rule. Some unaffected sections or provisions have been removed from the rule and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * ".

Commented [JSJ2]:
The stated adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule by the Board, and the Colorado Register publication dates.

The anticipated dates are based on the annual rulemaking schedule (regulatory agenda) for the Department which may be found online.

of the most recent effective date of this Part 7 (~~August 2020~~**December 15, 2022**), and not later amendments or editions of the incorporated material.

[* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

* * *

7.2 Definitions.

As used in this part, these terms have the definitions set forth as follows:

* * *

"Authorized medical physicist" (AMP) means an individual who meets the requirements of Appendix 7B; or

(1) Is identified as an authorized medical physicist or teletherapy physicist on:

a. A specific medical **use** license issued by the Department, NRC, or Agreement State;

b. A medical use permit issued by an NRC master material ~~license~~**licensee**;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee; or

d. A permit issued by an NRC master material license broad scope medical use ~~license~~**permittee.**

"Authorized nuclear pharmacist" (ANP) means a pharmacist who meets the requirements of Appendix 7C; or

(1) Is identified as an authorized nuclear pharmacist on:

a. A specific license issued by the Department, NRC, or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by an NRC master material ~~license~~**licensee** that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use ~~permitee~~**permittee** that authorizes medical use or the practice of nuclear pharmacy; or

(2) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(3) Is designated as an authorized nuclear pharmacist in accordance with Part 3.

Commented [JSJ3]: Select definitions in 7.2 are updated for consistency with federal rule language and for consistency with formatting of Colorado rule.

Commented [JSJ4]: Minor wording corrections are made, consistent with the current language in 10 CFR Part 35.2.

Commented [JSJ5]: Minor wording corrections are made, consistent with the current language in 10 CFR Part 35.2.

"Authorized user" (AU) means a physician, dentist, or podiatrist who meets the applicable requirements of Appendix 7D through Appendix 7M; or

(1) Is identified as an authorized user on:

a. A Department, NRC, or Agreement State license that authorizes the medical use of radioactive material;

b. A permit issued by an NRC master material ~~license~~**licensee** that is authorized to permit the medical use of radioactive material;

c. A permit issued by an NRC 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 an NRC master material license broad scope ~~permitee~~**permittee** that is authorized to permit the medical use of radioactive material.

* * *

"Ophthalmic physicist" means an individual who:

(1) Meets the requirements in 7.41.6.1(2) and 7.65; and

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

a. Specific medical use license issued by the Department, NRC or an Agreement State;

b. Permit issued by the Department, NRC or Agreement State broad scope medical use licensee;

c. Medical use permit issued by a NRC master material licensee; or

d. Permit issued by a NRC master material ~~licensee~~**license** broad scope medical use permittee.

* * *

"Sealed Source and Device Registry" means the national registry that contains **all** the registration certificates, ~~maintained~~**generated** by **both** the Nuclear Regulatory Commission **and the Agreement States**, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

* * *

7.3.1.1 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 Department, an Agreement State or NRC, or as allowed in ~~7.3.1.1 or~~ 7.3.1.2.

* * *

Commented [JSJ6]:
Minor wording corrections are made, consistent with the current language in 10 CFR Part 35.2.

Commented [JSJ7]:
Updated for consistency with similar phrasing in other proposed changes in this rule due to recent changes in federal rule.

Note - we believe that current wording in federal rule (10 CFR 35.2) for this provision is incorrect and inconsistent with other recent federal rule changes. This proposed change will be verified with NRC.

NRC Compatibility B

Commented [JSJ8]:
Definition is updated for clarity and consistency with language in 10 CFR Part 35.2.

Commented [JSJ9]:
Circular reference to 7.3.1.1 is not needed and is therefore deleted.

7.3.2.3 A licensee not authorized pursuant to **Part 3, Section** 3.11 shall apply for and receive approval of a specific amendment to its Department license before conducting research involving human subjects;

* * *

7.3.4.5 An applicant that satisfies the requirements specified in **Part 3, Section** 3.11 may apply for a Type A specific license of broad scope.

Commented [JSJ10]: Language updated for consistency with formatting of other radiation regulations.

* * *

7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's facility as a restricted area while radioactive material is present. For each location where radioactive materials will be routinely used, the licensee shall provide to the Department:

(1) A diagram of the location of use, including information about the placement of required postings; and

(2) Calculation(s) or survey(s) results that demonstrate compliance with applicable dose limits in **Part 4, Sections** 4.14 and 4.15 at the location of use.

7.3.5.8 The mobile medical service shall ensure that:

(1) Supervision by an authorized user is in accordance with 7.10.1;

(2) Radiation exposures to the client's personnel working in the client facility are:

(a) Below the dose limits to members of the public listed in **Part 4, Section** 4.14; or

(b) The client's personnel are instructed as described in **Part 10, Section** 10.3 and monitored for exposure in accordance with **Part 4, Section** 4.18 unless the licensee can demonstrate that **Section** 4.18 does not apply.

* * *

7.3.6 A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 3 of these regulations, is exempt from:

Commented [JSJ11]: Comma added.

* * *

7.4 License amendments.

A licensee shall apply for and must receive a license amendment:

7.4.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this part but is not authorized on the licensee's current license issued under this part;

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

7.4.2.1 For an authorized user, an individual who meets the requirements in Appendix 7P and one or more of the following: Section 7D1 of Appendix D, Section 7E1 of Appendix E,

Section 7F1 of Appendix F, Section 7G1 of Appendix 7G, Section 7H1 of Appendix 7H, Section 7K1 of Appendix K, Section 7J1 of Appendix J, or Section 7M1 of Appendix M;

7.4.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in Section 7C1 of Appendix 7C and 7.65;

7.4.2.3 For an authorized medical physicist, an individual who meets the requirements in Section 7B1 of Appendix 7B and 7.65;

7.4.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist ~~on~~:

(1) **On a** ~~A~~ NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) **On a** ~~A~~ permit issued by a NRC 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;

(3) On a permit issued by a NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

* * *

7.5 Notifications and maintenance of records.

* * *

7.5.2 A licensee shall notify the Department in writing no later than 30 days after:

* * *

7.5.2.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in **Part 3, Section** 3.15.2 of these regulations; or

* * *

7.7 Authority and responsibilities for the radiation protection program

7.7.1 In addition to the radiation protection program requirements of **Part 4, Section** 4.5 of these regulations, a licensee's management shall approve in writing:

* * *

7.10 Supervision.

7.10.1 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 7.3.1.2(1) shall:

Commented [JSJ12]:
Minor wording corrections are made, consistent with the language in 10 CFR Part 35.13**.

[**NOTE: Colorado made NRC aware of a likely error in 10 CFR Part 35 during the drafting of the rule. The provisions of 35.13(b)(4)(i) through (iv) in the official CFR (which parallel 7.4.2.4(1)-(4)) appear to have been inadvertently deleted from the final federal rule in 2018. NRC is now aware of this issue and has indicated they will be initiating a rulemaking to correct this error in late 2022.]

Commented [JSJ13]:
Text is formatted in Section 7.10 for alignment purposes.

7.10.1.1 In addition to the requirements of **Part 10, Section** 10.3 of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Part 7, and license conditions with respect to the use of radioactive material; and

7.10.1.2 Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Part 7, and license conditions with respect to the medical use of radioactive material.

7.10.2 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 7.3.1.2(2), shall:

7.10.2.1 In addition to the requirements of **Part 10, Section** 10.3, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and

7.10.2.2 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, the written radiation protection procedures, the regulations of Part 7, and license conditions.

* * *

7.23 Report and notification of a dose to an embryo/fetus or a nursing child

7.23.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) 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.

7.23.2 A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

7.23.2.1 Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or

7.23.2.2 Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

7.23.3 The licensee shall notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

7.23.4 The licensee shall submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

7.23.4.1 The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

Commented [JSJ14]: In Section 7.23, text is formatted for alignment purposes along with removal of unneeded/excess space.

(4) Why the event occurred;

(5) The effect on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken, or are planned, to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

7.23.4.2 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.

Commented [JSJ15]: Remove unneeded space between 7.23.4.2 and 7.23.4.3; and align/format text.

7.23.5 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 24 hours after discovery of an event that would require reporting under 7.23.1 or 7.23.2, 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. 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 24 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 7.23.5, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, 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.

7.23.6 A licensee shall:

7.23.6.1 Annotate a copy of the report provided to the Department with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

7.23.7 A copy of the record required under 7.23.6 shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

* * *

Section F – Sealed Sources for Diagnosis

7.40 Use of sealed sources and medical devices for diagnosis.

7.40.1 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.

7.40.2 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.

7.40.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with ~~and~~**an** active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

Commented [JSJ16]: Correction of typographical error.

7.40.4 Training for use of sealed sources and medical devices for diagnosis.

The licensee shall require an authorized user under 7.40 to meet the requirements of Appendix 7J.

Section G – Manual Brachytherapy

7.41 Calibration measurements of brachytherapy sources.

Commented [JSJ17]: Section 7.41 is formatted for alignment of text.

7.41.1 Before the first medical use of a brachytherapy source, a licensee shall have:

7.41.1.1 Determined the source output or activity using a dosimetry system that meets the requirements of 7.53;

7.41.1.2 Determined source positioning accuracy within applicators; and

7.41.1.3 Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 7.41.1.1 and 7.41.1.2.

7.41.2 Instead of a licensee making its own measurements as required in 7.41.1, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 7.41.1.

7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical decay at intervals consistent with 1 percent physical decay.

7.41.4 An authorized medical physicist shall perform or review the measurements and calculations made pursuant to 7.41.1, 7.41.2, or 7.41.3.

7.41.5 A licensee shall retain a record of each calibration as follows:

7.41.5.1 A licensee shall maintain a record of the calibrations of brachytherapy sources required by 7.41.1 for 3 years after the last use of the source.

7.41.5.2 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.

7.41.6 Strontium-90 sources for ophthalmic treatments.

7.41.6.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 7.41.6.2 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 NRC or an Agreement State; permit issued by a NRC or Agreement State broad scope medical use licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material ~~licensee~~**license** 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 1 year 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 7.41.1 through 7.41.5.

7.41.6.2 The individuals who are identified in 7.41.6.1 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 7.41.1 through 7.41.5; and

Commented [JSJ18]: Formatted for alignment of text.

Commented [JSJ19]: Updated for consistency with similar phrasing in other proposed changes in this rule due to recent amendments to federal rule.

Note - we believe that current wording in federal rule (10 CFR Part 35.433(a)(2)(i)) that is equivalent to this provision is inconsistent with other recent federal rule changes. This proposed change will be verified with NRC.

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(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 7.41.6.1 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.

7.41.6.3 Licensees must retain a record of the activity of each strontium-90 source as follows:

(1) A licensee shall maintain a record of the activity of a strontium-90 source required by 7.41.6 for the life of the source.

(2) The record must include:

(a) The date and initial activity of the source as determined under 7.41.1 through 7.41.5; and

(b) For each decay calculation, the date and the source activity as determined under 7.41.6.

* * *

7.43 Safety instruction.

In addition to the requirements of Part 10 of these regulations:

7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 7.26.

7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and include:

7.43.2.1 Size and appearance of the brachytherapy sources;

7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;

7.43.2.3 Patient or human research subject control;

7.43.2.4 Visitor control, including both;

(1) Routine visitation to hospitalized individuals in accordance with **Part 4, Section** 4.14.1.1; and

(2) Visitation authorized in accordance with **Part 4, Section** 4.14.3; and

7.43.2.5 Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

7.43.3 A licensee shall retain a record of individuals receiving safety instructions required by 7.43.1 and maintain such records for 3 years. The record must include a list of the topics covered, the date of the instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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Commented [JSJ21]: Section 7.43.2.5 is formatted for alignment of text.

7.44 Safety precautions.

7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be released in accordance with 7.26, a licensee shall:

7.44.1.1 Not place the patient or the human research subject in the same room with a patient who is not receiving radiation therapy;

7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on 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.

7.44.2 A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

7.44.2.1 Dislodged from the patient; or

7.44.2.2 Lodged within the patient following removal of the source applicators.

7.44.3 A licensee shall notify the RSO, 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.

* * *

7.47 Therapy-related computer systems.

7.47.1 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.

7.47.2 At a minimum, the acceptance testing required by 7.47.1 shall include, as applicable, verification of:

7.47.2.1 The source-specific input parameters required by the dose calculation algorithm;

7.47.2.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.47.2.3 The accuracy of isodose plots and graphic displays; and

7.47.2.4 The accuracy of the software used to determine radioactive source positions from radiographic images.

Section H - Photon Emitting Remote Afterloader Units, Teletheraphy Units, and Gamma Stereotactic Radiosurgery Units

7.48 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

7.48.1 A licensee must only use sealed sources:

7.48.1.1 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

Commented [JSJ22]:
Section 7.44 is formatted for alignment of text.

Commented [JSJ23]:
Language added for clarity and consistency with the current 10 CFR Part 35.457.

Section 7.47.2 has also been formatted for alignment of text.

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Section 7.48 is formatted for alignment of text. There are no changes to rule text or requirements.

7.48.1.2 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 U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

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

7.48.2.1 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

7.48.2.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.

7.48.3 Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

The licensee shall require an authorized user under 7.48 to meet the requirements of Appendix 7M.

* * *

7.58 Periodic spot checks for teletherapy units.

7.58.1 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:

7.58.1.1 Timer accuracy, and timer linearity over the range of use;

7.58.1.2 “On off” error;

7.58.1.3 The coincidence of the radiation field and the field indicated by the light beam localizing device;

7.58.1.4 The accuracy of all distance measuring and localization devices used for medical use;

7.58.1.5 The output for one typical set of operating conditions measured with the dosimetry system described in 7.53; and

7.58.1.6 The difference between the measurement made in 7.58.1.5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

7.58.2 A licensee shall perform spot checks required by 7.58.1 in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the output spot-check measurements.

7.58.3 A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall ~~promptly~~ notify the licensee **as soon as possible** in writing of the results of each spot check.

Commented [JSJ25]:
Remove unneeded comma in 7.58.1.

Where needed, 7.58.1 through 7.58.6.9 has been formatted for alignment of text.

Commented [JSJ26]:
Language clarified for consistency with 10 CFR Part 35.642(c).

7.58.4 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:

7.58.4.1 Electrical interlocks at each teletherapy room entrance;

7.58.4.2 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;

7.58.4.3 Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

7.58.4.4 Viewing and intercom systems;

7.58.4.5 Treatment room doors from inside and outside the treatment room; and

7.58.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned “off”.

7.58.5 If the results of the checks required in 7.58.4 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.

7.58.6 A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.4, and a copy of the procedures required by 7.58.2 for 3 years. The record shall include:

7.58.6.1 The date of the spot check;

7.58.6.2 The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

7.58.6.3 An assessment of timer linearity and constancy;

7.58.6.4 The calculated “on off” error;

7.58.6.5 A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device

7.58.6.6 The determined accuracy of each distance measuring or localization device;

7.58.6.7 The difference between the anticipated output and the measured output;

7.58.6.8 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

7.58.6.9 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.

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PART 7, APPENDIX 7A: TRAINING FOR RADIATION SAFETY OFFICER (RSO) AND ASSOCIATE RADIATION SAFETY OFFICER (ARSO)

Except as provided in Appendix 7P, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer (ARSO) as provided in 7.7 to be an individual who:

7A1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in 7A4 of this Appendix. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7A1.1

(1) 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 20 college credits in physical science;

(2) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics;

and

(3) 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

7A1.2

(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;

and

(2) Have 2 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 an Agreement State or NRC;

or

(b) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for Authorized Users in Appendix 7P, Appendix 7E or Appendix 7F;

and

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Prior to final publication, ensure that this Appendix **and all subsequent appendices** begin at the top of the page.

(3) 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

7A2

7A2.1 Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(e) Radiation dosimetry;

and

(2) One year of full-time radiation safety experience, under the supervision of the individual identified as the RSO, on a NRC or an Agreement State license or permit issued by a NRC 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 NRC or an Agreement State license or permit issued by a NRC master material licensee. The full-time radiation safety experience must involve the following:

(a) Shipping, receiving, and performing related radiation surveys;

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

(c) Securing and controlling radioactive material;

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

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

(f) Using emergency procedures to control radioactive material; and

(g) Disposing of radioactive material;

and

7A2.2 This individual must obtain a written attestation, signed by a preceptor RSO or ARSO 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 RSO or an ARSO. The written attestation must state that the individual has satisfactorily completed the requirements in 7A2.1 and 7A4 of Appendix 7A and is able to independently fulfill the radiation safety related duties as a RSO or as an ARSO for a medical use license;

or

7A3

7A3.1 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State under Appendix 7B, Section 7B1, 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 RSO or an ARSO, and meets the requirements in 7A4.

or

7A3.2 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Department, NRC or an Agreement State license, a permit issued by a NRC master material ~~license~~**licensee**, a permit issued by a NRC or an Agreement State licensee of broad scope, or a permit issued by a NRC master material **license** broad scope ~~permitee~~**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 RSO or ARSO, and meets the requirements in 7A4;

or

7A3.3 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 permit issued by a NRC master material ~~license~~**licensee**. The individual must also meet the requirements in 7A4.

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Minor technical correction/update for consistency with federal regulations in 10 CFR 35.50(c)(3).

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and

7A4 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 an RSO, an Associate RSO, 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.

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PART 7, APPENDIX 7C: TRAINING FOR AND AUTHORIZED NUCLEAR PHARMACIST (ANP)

Except as provided in Appendix 7P, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

7C1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

7C1.1 Have graduated from a pharmacy program accredited by the **Accreditation Council for Pharmacy Education (ACPE) (previously named the** American Council on Pharmaceutical Education**)** ~~(ACPE)~~ or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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Minor technical correction/update for consistency with 2021 federal regulation changes to 10 CFR 35.55(a)(1).

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PART 7, APPENDIX 7P: TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR PHARMACIST.

7P1

7P1.1 An individual identified on a Department, NRC or an Agreement State license or a permit issued by a Department, NRC or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before August 14, 2020 need not comply with the training requirements of Appendix 7A, 7B, or 7C, respectively, except the Radiation Safety Officers and authorized medical physicists identified in 7P1.1 must meet the training requirements in 7A4 of Appendix 7A or 7B3 of Appendix 7B, as appropriate, for any material or uses for which they were not authorized prior to this date.

7P1.2 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 Appendix 7A to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an NRC or an Agreement State license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

7P1.3 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 Appendix 7B, for those materials and uses that these individuals performed on or before October 24, 2005.

7P1.4 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 NRC, need not comply with the training requirements of Appendix 7A, 7B, or 7C 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 during the time period identified in 7P1.4, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of the regulations.

7P2

7P2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement

State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before August 14, 2020, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Sections D through H.

7P2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued ~~by~~**in accordance with** a NRC master material ~~license of~~ broad scope **license** on or before October 24, 2005, need not comply with the training requirements of Sections D through H for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

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Minor technical correction for wording consistency with 2021 federal regulation changes to 10 CFR 35.57(b)(2).

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