

This is an amendment to 20.3.7.7 NMAC, Sub-Section E effective XX/XX/2022.

20.3.7.7 DEFINITIONS:

A. "Address of use" means the building or buildings that are identified on the license and where radioactive material may be prepared, received, used or stored.

B. "Area of use" means a portion of an address of use that has been set aside for the purpose of preparing, receiving, using or storing radioactive material.

C. "Associate Radiation Safety Officer (ARSO)" means an individual who

(1) Meets the requirements in §§ 35.50 and 35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct 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 Commission or an Agreement State;
or

(b) A medical use permit issued by a Commission master material licensee.

~~C~~D. "Authorized medical physicist" means an individual who:

(1) meets the requirements in Subsection B of 20.3.7.714 NMAC, incorporating 10 CFR 35.51(a), and Subsection E of 20.3.7.714 NMAC; or

(2) 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 a NRC master material licensee;

(c) a permit issued by the department, NRC or agreement state broad scope medical

use licensee; or

(d) a permit issued by a NRC master material license broad scope medical use

permittee.

~~D~~E. "Authorized nuclear pharmacist" means a pharmacist who:

(1) meets the requirements in Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(a), and Subsection E of 20.3.7.714 NMAC; or

(2) 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 a NRC master material licensee that authorizes medical use

or the practice of nuclear pharmacy;

(c) a permit issued by a department, 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 a NRC 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 Subparagraph (e) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC.

~~E~~F. "Authorized user" means a physician, dentist or podiatrist who:

(1) meets the requirements in Subsection E of 20.3.7.714 NMAC and any of the following subsections of 20.3.7.714 NMAC: Subsection F, incorporating 10 CFR 35.190(a); Subsection G, incorporating 10 CFR 35.290(a); Subsection H, incorporating 10 CFR 35.390(a); Subsection I, incorporating 10 CFR 35.392(a); Subsection J, incorporating 10 CFR 35.394(a); Subsection L, incorporating 10 CFR 35.490(a); Subsection N, incorporating 10 CFR 35.590(a); or Subsection O, incorporating 10 CFR 35.690(a); or

(2) 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 a NRC master material licensee that is authorized to permit the medical use of radioactive material;

(c) a permit issued by a department, 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 a NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

[F]G. “**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.

[G]H. “**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.

[H]I. “**Client's address**” means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with Subsection J of 20.3.7.703 NMAC.

[I]J. “**Dedicated check source**” means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

[J]K. “**Dentist**” means an individual licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to practice dentistry.

[K]L. “**High dose-rate remote afterloader**”, as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

[L]M. “**Low dose-rate remote afterloader**”, as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to two grays (200 rads) per hour at the point or surface where the dose is prescribed.

[M]N. “**Management**” means the chief executive officer or other individual having the authority to manage, direct or administer the licensee's activities or those persons' delegate or delegates.

[N]O. “**Manual brachytherapy**”, as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, 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.

[O]P. “**Medical event**” means an event that meets the criteria in Paragraph (1) or (2) of Subsection A of 20.3.7.716 NMAC.

[P]Q. “**Medical institution**” means an organization in which more than one medical discipline is practiced.

[Q]R. “**Medical use**” means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

[R]S. “**Medium dose-rate remote afterloader**”, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than two grays (200 rads) per hour, but less than or equal to 12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

[S]T. “**Mobile medical service**” means the transportation of radioactive material to and its medical use at the client's address.

[T]U. “**NIST**” means the national institute of standards and technology which is the standards-defining agency of the United States government, formerly the national bureau of standards. It is one of three agencies that fall under the technology administration (www.technology.gov), a branch of the United States commerce department that is devoted to advancing American economic growth through the use of technology.

V. “**Ophthalmic physicist**” means an individual who—

(1) Meets the requirements in § 35.433(a)(2) and § 35.59; and

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

(a) Specific medical use license issued by the Commission or an

Agreement State;

(b) Permit issued by a Commission or Agreement State broad scope

medical use licensee;

(c) Medical use permit issued by a Commission master material licensee;

or

(d) Permit issued by a Commission master material licensee broad scope

medical use permittee.

[U]W. “**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.

[V]X. “**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.

~~[W]~~Y. **“Pharmacist”** means an individual licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to practice pharmacy.

~~[X]~~Z. **“Physician”** means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

~~[Y]~~AA. **“Podiatrist”** means an individual licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to practice podiatry.

~~[Z]~~BB. **“Positron emission tomography (PET) radionuclide production facility”** is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

~~[AA]~~CC. **“Preceptor”** means an individual who provides, directs or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~or a~~ R~~[r]~~adiation S~~[s]~~afety O~~[o]~~fficer, or an Associate Radiation Officer.

~~[BB]~~DD. **“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 20.3.7.704 NMAC and 20.3.7.705 NMAC.

~~[CC]~~EE. **“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.

~~[DD]~~FF. **“Pulsed dose-rate remote afterloader”**, as used in this part, 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.

~~[EE]~~GG. **“Radiation safety officer”** means an individual who:

- (1) meets the requirements in Subsection E of 20.3.7.714 NMAC and either Subsection A of 20.3.7.714 NMAC, incorporating 10 CFR 35.50(a), or Subsection A of 20.3.3.714 NMAC, incorporating 10 CFR 35.50(c)(1); or
- (2) is identified as a radiation safety officer on:
 - (a) a specific medical use license issued by the department, NRC or agreement state; or
 - (b) a medical use permit issued by a NRC master material licensee.

~~[FF]~~HH. **“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.

~~[GG]~~II. **“Structured educational program”** means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

~~[HH]~~JJ. **“Teletherapy”**, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

~~[II]~~KK. **“Temporary job site”** means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

~~[JJ]~~LL. **“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.

~~[KK]~~MM. **“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.

~~[LL]~~NN. **“Treatment site”** means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

~~[MM]QQ.~~ **“Type of use”** means use of radioactive material under the following sections: 20.3.7.704 NMAC, 20.3.7.705 NMAC, 20.3.7.708 NMAC, 20.3.7.710 NMAC, 20.3.7.711 NMAC, 20.3.7.712 NMAC and 20.3.7.713 NMAC.

~~[NN]PP.~~ **“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.

~~[OO]QQ.~~ **“Written directive”** 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 object, as specified in Subsection G of 20.3.7.702 NMAC.

[20.3.7.7 NMAC - Rp, 20 NMAC 3.1.7.701, 04/30/2009, A, XX/XX/2022]

This is an amendment to 20.3.7.702 NMAC, Sub-Sections A, G and H effective XX/XX/2022.

20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS:

A. Radiation safety officer.

(1) A licensee or licensee’s management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing a 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.

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

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

- (a) identify radiation safety problems;
- (b) initiate, recommend or provide corrective actions;
- (c) prevent or order the cessation of unsafe operations; and
- (d) verify implementation of corrective actions.

(4) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer, under Subsections A and E of 20.3.7.714 NMAC, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in Paragraph (3) of this subsection, if the licensee takes the actions required in Paragraphs (1), (2), (3) and (5) of this subsection and notifies the department in accordance with Paragraph (2) of Subsection G of 20.3.7.700 NMAC.

(5) A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with Paragraph (4) of this subsection, 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.

B. Authority and responsibilities for the radiation protection program. In addition to the radiation protection program requirements of 20.3.4.404 NMAC, a licensee or licensee's management shall approve in writing:

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

(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 Subsection E of this section.

C. Record keeping. A licensee shall retain a record of actions taken under Subsections A and B of this section in accordance with Subsection A of 20.3.7.715 NMAC.

D. Radiation safety committee. Licensees that are authorized for two or more different types of use of radioactive material under 20.3.7.708, 20.3.7.710 and 20.3.7.711 NMAC or two or more types of units under

20.3.7.711 NMAC shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The radiation safety committee shall meet the following administrative requirements.

(1) The radiation safety 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 radiation safety committee may include other members who the licensee considers appropriate.

(2) The radiation safety committee shall meet at least once each calendar quarter. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative.

(3) The licensee shall maintain minutes of each radiation safety committee meeting, promptly provide each member with a copy of the meeting minutes and retain one copy for the duration of the license.

(4) To oversee the use of licensed material, the radiation safety committee shall:

(a) review and verify the training and experience documentation (such as the board certification, preceptor statement(s), or any additional required training) and approve or disapprove any individual who is to be listed on a license as an authorized user, an authorized nuclear pharmacist, a radiation safety officer or an authorized medical physicist before submitting a license application or request for amendment or renewal;

(b) review and verify the training and experience documentation (such as the board certification, preceptor statement(s), the license or the permit identifying an individual as an authorized user, authorized nuclear pharmacist, authorized medical physicist or a radiation safety officer) and approve or disapprove any individual prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, a radiation safety officer or an authorized medical physicist;

(c) review, on the basis of safety, and approve or disapprove each proposed method of use of radioactive material;

(d) review, on the basis of safety, and approve or disapprove with the advice and consent of the radiation safety officer and the management representative, licensee's procedures and radiation protection program changes prior to submittal to the department for licensing action;

(e) review quarterly records of the radiation protection program indicating non-ALARA occurrences and all incidents and medical events involving radioactive material with respect to cause and subsequent actions taken; and

(f) review, annually, with the assistance of the radiation safety officer, the radiation protection program.

E. Radiation protection program changes.

(1) A licensee may revise its radiation protection program without department approval if:

(a) the revision does not require a license amendment under Subsection F of 20.3.7.700 NMAC;

(b) the revision is in compliance with the requirements in 20.3 NMAC and the license;

(c) the revision has been reviewed and approved by the radiation safety officer and licensee's management; and

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

(2) A licensee shall retain a record of each change in accordance with Subsection B of 20.3.7.715 NMAC.

F. Supervision.

(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 Subparagraph (a) of Paragraph (2) of Subsection D of 20.3.7.700 NMAC, shall:

(a) in addition to the requirements in 20.3.10.1002 NMAC, instruct the supervised individual in the licensee's written radiation protection program and quality assurance procedures, written directive procedures, requirements of this chapter and license conditions with respect to the use of radioactive material;

(b) require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection program and quality assurance procedures established by the licensee, written directive procedures, the requirements in 20.3 NMAC and license conditions with respect to the medical use of radioactive material;

(c) require the supervising authorized user to periodically review the supervised individual's use of radioactive material and the records kept to reflect this use; and

(d) document the performance of the supervised individual with respect to the medical use of radioactive material.

(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 Subparagraph (b) of Paragraph (2) of Subsection D of 20.3.7.700 NMAC shall:

(a) in addition to the requirements in 20.3.10.1002 NMAC, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material;

(b) 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 licensee's written radiation protection program and quality assurance procedures, the requirements of 20.3 NMAC and license conditions;

(c) require the supervising authorized nuclear pharmacist or authorized user to periodically review the work of the supervised individual as it pertains to radiation safety and quality assurance in preparing radioactive material for medical use and the records kept to reflect that work; and

(d) document the performance of the supervised individual with respect to the medical use of radioactive material.

(3) A licensee who permits supervised activities under Paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

G. Written directive. Each applicant or licensee under this part, as applicable, shall establish and maintain written directive procedures to provide high confidence that byproduct [radioactive] material or radiation from radioactive material will be administered as directed by the authorized user. The written directive procedures must include written policies and procedures that meet the following specific requirements.

(1) A written directive must be prepared, dated and signed by an authorized user before the administration of I-131 sodium iodide of quantities greater than 30 microcuries (1.11 megabecquerels), 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 documenting the oral directive must be prepared, dated and signed by the authorized user within 48 hours of the oral directive.

(2) 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 byproduct [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, provided that the oral revision is documented as soon as possible in writing in the patient's record. A revised written directive documenting the oral revision must be prepared, dated and signed by the authorized user within 48 hours of the oral revision.

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

(a) for any administration of quantities greater than 30 microcuries (1.11 megabecquerels) of I-131 sodium iodide: the dosage;

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

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

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

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

(f) For permanent implant brachytherapy:

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

(ii) 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; or [~~for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders, before implantation: treatment site, the radionuclide and dose; and 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).~~]

(g) for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders: before implantation: the treatment site, [the] radionuclide and dose; and 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 date.

(4) 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 byproduct 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 48 hours of the oral revision.

~~(5)~~(4) The licensee shall retain a copy of the written directive in accordance with Subsection C of 20.3.7.715 NMAC.

H. Procedures for administrations requiring a written directive.

(1) For any administration requiring a written directive, the licensee shall develop, implement and maintain written procedures to provide high confidence that:

(a) the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive before each administration; and

(b) each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by Paragraph (1) of this subsection must address the following items that are applicable to the licensee's use of radioactive material:

(a) verifying the identity of the patient or human research subject;

(b) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(c) checking both manual and computer-generated dose calculations; and

(d) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 20.3.7.711 NMAC or 20.3.7.713 NMAC.

(e) Determining if a medical event, as defined in 20.3.7.716 NMAC and 10 CFR 35.3045, has occurred; and

(f) Determining, for permanent implant brachytherapy, within 60 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.

(3) A licensee shall retain a copy of the procedures required under Paragraph (1) of this subsection in accordance with Subsection D of 20.3.7.715 NMAC.

I. Suppliers of sealed sources or devices for medical use. For medical use, a licensee may only use:

(1) sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under Subsection K of 20.3.3.315 NMAC or equivalent requirements of NRC or an agreement state;

(2) sealed sources or devices non-commercially transferred from a 20.3.7 NMAC licensee, a NRC or agreement state licensee; or

(3) teletherapy sources manufactured and distributed in accordance with a license issued under 20.3.3 NMAC or the equivalent requirements of NRC or an agreement state.

[20.3.7.702 NMAC - Rp, 20 NMAC 3.1.7.702, 04/30/2009, A XX/XX/2022]

This is an amendment to 20.3.7.706 NMAC, Sub-Section B effective XX/XX/2022.

20.3.7.706 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82 AND STRONTIUM-85 CONCENTRATIONS:

A. Maximum concentrations. A licensee may not administer to humans a radiopharmaceutical containing:

- (1) more than 0.15 microcurie of molybdenum-99 per each millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per each megabecquerel of technetium-99m); or
- (2) more than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82).

B. Measurement.

(1) A licensee preparing technetium-99m radiopharmaceutical from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration ~~[of the first eluate after the receipt of the generator to demonstrate compliance with Subsection A of this section]~~ in each eluate from a generator to demonstrate compliance with Subsection A of this section.

(2) 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 Subsection A of this section.

C. Record keeping. If a licensee is required to measure the molybdenum-99 concentration or strontium-85 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with Subsection M of 20.3.7.715 NMAC.

D. Reporting. The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with subsection D of 20.3.7.716 NMAC and § 35.3204.

[20.3.7.706 NMAC - Rp, 20 NMAC 3.1.7.706, 04/30/2009, A, XX/XX/2022]

This is an amendment to 20.3.7.708 NMAC effective XX/XX/2022.

20.3.7.708 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed byproduct ~~[radioactive]~~ material identified in 10 CFR 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is ~~[either]~~:

A. Obtained from a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC or equivalent agreement state or NRC requirements; or

B. Prepared by:

- (1) an authorized nuclear pharmacist;
- (2) a physician who is an authorized user and who meets the requirements specified in either Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390; or
- (3) an individual under the supervision, as specified in Subsection F of 20.3.7.702 NMAC, of the authorized nuclear pharmacist in Paragraph (1) of this subsection or the physician who is an authorized user in Paragraph (2) of this subsection; or

C. Obtained from and prepared by a department, NRC 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 FDA; or

D. Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new protocol accepted by FDA.

[20.3.7.708 NMAC - Rp, 20 NMAC 3.1.7.708, 04/30/2009, A, XX/XX/2022]

This is an amendment to 20.3.7.710 NMAC, Sub-Section A and G effective XX/XX/2022.

20.3.7.710 MANUAL BRACHYTHERAPY:

A. Use of sources for manual brachytherapy. The regulations of the NRC set forth in 10 CFR 35.400 are hereby incorporated by reference. ~~[A licensee shall use only brachytherapy sources for therapeutic medical uses:~~

- ~~(1) as approved in the sealed source and device registry; or~~
- ~~(2) in research in accordance with an active investigational device exemption application accepted by the FDA provided the requirements of Paragraph (1) of Section I of 20.3.7.702 NMAC are met.]~~

B. Surveys after source implant and removal.

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

(2) Immediately after removing the last temporary implant source from a patient or a human research subject, 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.

(3) A licensee shall retain a record of the surveys required by Paragraphs (1) and (2) of this subsection in accordance with Subsection P of 20.3.7.715 NMAC.

C. Brachytherapy sources accountability.

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

(2) 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.

(3) A licensee shall maintain a record of the brachytherapy source accountability in accordance with Subsection Q of 20.3.7.715 NMAC.

D. Safety instructions. In addition to the requirements in 20.3.10.1002 NMAC:

(1) the licensee shall provide radiation safety instructions, initially and at least annually, to personnel caring for patients or the human research subjects who are receiving brachytherapy and cannot be released under Subsection I of 20.3.7.703 NMAC; to satisfy this requirement, the instructions must be commensurate with the duties of the personnel and include:

(a) the size and appearance of the brachytherapy sources;

(b) safe handling of the brachytherapy sources and shielding instructions;

(c) a patient or human research subject control;

(d) visitor control, including both routine visitation of hospitalized individuals in accordance with Paragraph (1) of Subsection A of 20.3.4.413 NMAC, and visitation authorized in accordance with Subsection F of 20.3.4.413 NMAC; and

(e) notification of the radiation safety officer, or their designee, and an authorized user if the patient or human research subject has a medical emergency or dies;

(2) a licensee shall retain a record of individuals receiving safety instructions in accordance with Subsection O of 20.3.7.715 NMAC.

E. Safety precautions.

(1) For each patient or human research subject receiving brachytherapy and cannot be released under Subsection I of 20.3.7.703 NMAC a licensee shall:

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

(b) visibly post the patient's or human research subject's door with a "Radioactive Materials" sign; and

(c) 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.

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

(a) dislodged from the patient; and

(b) lodged within the patient following removal of the source applicators.

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

F. Calibration measurements of brachytherapy sources.

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

(a) determined the source output or activity using a dosimetry system that meets the requirements of Paragraph (1) of Subsection F of 20.3.7.711 NMAC;

(b) determined source positioning accuracy within applicators; and

(c) used published protocols currently accepted by nationally recognized bodies to meet the requirements of Subparagraphs (a) and (b) of this paragraph.

(2) Instead of a licensee making its own measurements as required in Paragraph (1) of this subsection, 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 Paragraph (1) of this subsection.

(3) A licensee shall mathematically correct the outputs or activities determined in Paragraph (1) of this subsection for physical decay at intervals consistent with one percent physical decay.

(4) A licensee shall retain a record of each calibration in accordance with Subsection R of 20.3.7.715 NMAC.

G. Decay of strontium-90 sources for ophthalmic treatments. The regulations of the NRC set forth in 10 CFR 35.433 are hereby incorporated by reference.

~~[(1) 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 Subsection F of 20.3.7.710 NMAC.~~

~~(2) A licensee shall retain a record of the activity of each strontium 90 source in accordance with Subsection S of 20.3.7.715 NMAC.]~~

H. Therapy-related computer systems. 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:

- (1) the source-specific input parameters required by the dose calculation algorithm;
- (2) the accuracy of dose, dwell time and treatment time calculations at representative points;
- (3) the accuracy of isodose plots and graphic displays; and
- (4) the accuracy of the software used to determine sealed source positions from radiographic images.

[20.3.7.710 NMAC - Rp, 20 NMAC 3.1.7.709, 04/30/2009, A, XX/XX/2022]

This is an amendment to 20.3.7.711 NMAC, Sub-Section D, O effective XX/XX/2022.

20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, THERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS:

A. 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:

- (1) as approved in the sealed source and device registry; or
- (2) in research in accordance with an active investigational device exemption application accepted by the FDA provided the requirements of Paragraph (1) of Subsection I of 20.3.7.702 NMAC are met.

B. Surveys of patients and human research subjects treated with a remote afterloader unit.

(1) 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.

(2) A licensee shall retain a record of these surveys in accordance with Subsection P of 20.3.7.715 NMAC.

C. Installation, maintenance, adjustment and repair.

(1) Only a person specifically licensed by the department, NRC 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).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, NRC 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.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the department, NRC, an agreement state or an authorized medical physicist shall install, replace, relocate or remove a sealed source(s) contained in the unit.

(4) 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 Subsection T of 20.3.7.715 NMAC.

D. Safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

- (1) A licensee shall:

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

(b) 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);

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

(d) 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:

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

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

(iii) 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.

(2) A copy of the procedures required by Subparagraph (d) of Paragraph (1) of this subsection must be physically located at the unit console.

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

(a) the location of the procedures required by Subparagraph (d) of Paragraph (1) of this subsection; and

(b) 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.

(4) 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, a licensee shall 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.

(5[4]) A licensee shall provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in:

(a) the procedures identified in Subparagraph (d) of Paragraph (1) of this subsection; and

(b) the operating procedures for the unit.

(6[5]) A licensee shall ensure that operators, authorized medical physicists and authorized users participate in drills of the emergency procedures, initially and at least annually.

(7[6]) A licensee shall retain a record of individuals receiving instruction required by Paragraph (5) of this subsection, in accordance with Subsection O of 20.3.7.715 NMAC.

(8[7]) A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) and Subparagraph (b) of Paragraph (4) of this subsection in accordance with Subsection U of 20.3.7.715 NMAC.

E. Safety precautions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

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

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

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

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

(c) 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.

(3) 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.

(4) 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.

(5) 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.

(6) In addition to the requirements specified in Paragraphs (1) through (5) of this subsection, a licensee shall:

- (a) for medium dose-rate and pulsed dose-rate remote afterloader units, require:
 - (i) 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
 - (ii) 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;
- (b) for high dose-rate remote afterloader units, require:
 - (i) an authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
 - (ii) 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;
- (c) 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;
- (d) notify the radiation safety officer, or their designee and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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

- (a) remains in the unshielded position; or
- (b) is lodged within the patient following completion of the treatment.

F. Dosimetry equipment.

(1) 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.

(a) The system must have been calibrated using a system or source traceable to the NIST and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American association of physicists in medicine. The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration.

(b) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been inter-compared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the American association of physicists in medicine. The results of the inter-comparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing 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.

(2) 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 (1) of this subsection. 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 (1) of this subsection.

(3) The licensee shall retain a record of each calibration, inter-comparison and comparison in accordance with Subsection V of 20.3.7.715 NMAC.

G. Full calibration measurements on teletherapy units.

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

- (a) before the first medical use of the unit;
- (b) before medical use under the following conditions:

(i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

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

(iii) 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

(c) at intervals not exceeding one year.

(2) To satisfy the requirement of Paragraph (1) of this subsection, full calibration measurements must include determination of:

(a) the output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

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

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

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

(e) on-off error; and

(f) the accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in Paragraph (1) of Subsection F of 20.3.7.711 NMAC to measure the output for one set of exposure conditions. The remaining radiation measurements required in Subparagraph (a) of Paragraph (2) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by Paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in Subparagraph (a) of Paragraph (2) of this subsection for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(6) Full calibration measurements required by Paragraph (1) of this subsection and physical decay corrections required by Paragraph (5) of this subsection must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with Subsection W of 20.3.7.715 NMAC.

H. Full calibration measurements on remote afterloader units.

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

(a) before the first medical use of the unit;

(b) before medical use under the following conditions:

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

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

(c) 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 75 days; and

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

(2) To satisfy the requirement of Paragraph (1) of this subsection, full calibration measurements must include, as applicable, determination of:

(a) the output within plus or minus five percent;

(b) source positioning accuracy to within plus or minus 1 millimeter;

(c) source retraction with backup battery upon power failure;

(d) length of the source transfer tubes;

(e) timer accuracy and linearity over the typical range of use;

(f) length of the applicators; and

(g) function of the source transfer tubes, applicators and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in Paragraph (1) of Subsection F of 20.3.7.711 NMAC to measure the output.

(4) A licensee shall make full calibration measurements required by Paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Paragraph (2) of this subsection, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Paragraphs (1) through (5) of this subsection.

(7) A licensee shall mathematically correct the outputs determined in Subparagraph (a) of Paragraph (2) of this subsection for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by Paragraph (1) of this subsection and physical decay corrections required by Paragraph (7) of this subsection must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with Subsection W of 20.3.7.715 NMAC.

I. Full calibration measurements on gamma stereotactic radiosurgery units.

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

(a) before the first medical use of the unit;

(b) before medical use under the following conditions:

(i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

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

(iii) 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

(c) 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.

(2) To satisfy the requirement of Paragraph (1) of this subsection, full calibration measurements must include determination of:

(a) the output within plus or minus three percent;

(b) relative helmet factors;

(c) isocenter coincidence;

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

(e) on-off error;

(f) trunnion centricity;

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

(h) helmet microswitches;

(i) emergency timing circuits; and

(j) stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in Paragraph (1) of Subsection F of 20.3.7.711 NMAC to measure the output for one set of exposure conditions. The remaining radiation measurements required in Subparagraph (a) of Paragraph (2) of this subsection of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by Paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in Subparagraph (a) of Paragraph (2) of this subsection at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by Paragraph (1) of this subsection and physical decay corrections required by Paragraph (5) of this subsection must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with Subsection W of 20.3.7.715 NMAC.

J. Periodic spot-checks for teletherapy units.

(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:

- (a) timer accuracy and timer linearity over the range of use;
- (b) on-off error;
- (c) the coincidence of the radiation field and the field indicated by the light beam localizing device;
- (d) the accuracy of all distance measuring and localization devices used for medical use;
- (e) the output for one typical set of operating conditions measured with the dosimetry system described in Paragraph (2) of Subsection F of 20.3.7.711 NMAC; and
- (f) the difference between the measurement made in Subparagraph (e) of this paragraph 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).

(2) A licensee shall perform measurements required by Paragraph (1) of this subsection in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(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:

- (a) electrical interlocks at each teletherapy room entrance;
- (b) 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);
- (c) source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
- (d) viewing and intercom systems;
- (e) treatment room doors from inside and outside the treatment room; and
- (f) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the checks required in Paragraph (4) of this subsection 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.

(6) A licensee shall retain a record of each spot-check required by Paragraphs (1) and (4) of this subsection, and a copy of the procedures required by Paragraph (2), in accordance with Subsection X of 20.3.7.715 NMAC.

K. Periodic spot-checks for remote afterloader units.

(1) 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:

- (a) before the first use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit on a given day;
- (b) before each patient treatment with a low dose-rate remote afterloader unit; and
- (c) after each source installation.

(2) A licensee shall perform the measurements required by Paragraph (1) of this subsection in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of Paragraph (1) of this subsection, spot-checks must, at a minimum, assure proper operation of:

- (a) electrical interlocks at each remote afterloader unit room entrance;
- (b) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
- (c) viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
- (d) emergency response equipment;
- (e) radiation monitors used to indicate the source position;
- (f) timer accuracy;
- (g) clock (date and time) in the unit's computer; and
- (h) decayed source(s) activity in the unit's computer.

(5) If the results of the checks required in Paragraph (4) of this subsection 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.

(6) A licensee shall retain a record of each check required by Paragraph (4) of this subsection and a copy of the procedures required by Paragraph (2) of this subsection in accordance with Subsection Y of 20.3.7.715 NMAC.

L. Periodic spot-checks for gamma stereotactic radiosurgery units.

(1) 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:

- (a) monthly;
- (b) before the first use of the unit on a given day; and
- (c) after each source installation.

(2) A licensee shall:

(a) perform the measurements required by Paragraph (1) of this subsection in accordance with written procedures established by the authorized medical physicist; that individual need not actually perform the spot check measurements;

(b) have the authorized medical physicist review the results of each spot-check within 15 days; the authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(3) To satisfy the requirements of Subparagraph (a) of Paragraph (1) of this subsection, spot-checks must, at a minimum:

- (a) assure proper operation of:
 - (i) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - (ii) helmet microswitches;
 - (iii) emergency timing circuits; and
 - (iv) stereotactic frames and localizing devices (trunnions); and
- (b) determine:
 - (i) the output for one typical set of operating conditions measured with the dosimetry system described in Paragraph (2) of Subsection F of 20.3.7.711 NMAC;
 - (ii) the difference between the measurement made above (Item (i) of Subparagraph (b) of Paragraph (3) of Subsection L of 20.3.7.711 NMAC) 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);
 - (iii) source output against computer calculation;
 - (iv) timer accuracy and linearity over the range of use;
 - (v) on-off error; and
 - (vi) trunnion centricity.

(4) To satisfy the requirements of Subparagraphs (b) and (c) of Paragraphs (1) of this subsection, spot-checks must assure proper operation of:

- (a) electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- (b) source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
- (c) viewing and intercom systems;
- (d) timer termination;
- (e) radiation monitors used to indicate room exposures; and

(f) emergency off buttons.

(5) A licensee shall arrange for the repair of any system identified in Paragraph (3) of this subsection that is not operating properly as soon as possible.

(6) If the results of the checks required in Paragraph (4) of this subsection 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) A licensee shall retain a record of each check required by Paragraphs (3) and (4) and a copy of the procedures required by Paragraph (2) of this subsection in accordance with Subsection Z of 20.3.7.715 NMAC.

M. Additional technical requirements for mobile remote afterloader units.

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

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

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

(2) In addition to the periodic spot-checks required by Subsection K of 20.3.7.711 NMAC, 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:

(a) electrical interlocks on treatment area access points;

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

(c) viewing and intercom systems;

(d) applicators, source transfer tubes and transfer tube-applicator interfaces;

(e) radiation monitors used to indicate room exposures;

(f) source positioning (accuracy); and

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

(3) In addition to the requirements for checks in Paragraph (2) of this subsection, 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.

(4) If the results of the checks required in Paragraph (2) of this subsection 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.

(5) A licensee shall retain a record of each check required by Paragraph (2) of this subsection in accordance with Subsection AA of 20.3.7.715 NMAC.

N. Radiation surveys.

(1) In addition to the survey requirements in Subsection H of 20.3.7.703 NMAC and 20.3.4.416 NMAC, a person subject to this section 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.

(2) The licensee shall make the survey required by Paragraph (1) of this subsection 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).

(3) A licensee shall retain a record of the radiation surveys required by Paragraph (1) of this subsection in accordance with Subsection BB of 20.3.7.715 NMAC.

O. Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(1) 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 5 years, whichever comes first,~~] to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the department, NRC or an agreement state.

(3) A licensee shall keep a record of the inspection and servicing in accordance with Subsection CC of 20.3.7.715 NMAC.

P. Therapy-related computer systems. 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:

- (1) the source-specific input parameters required by the dose calculation algorithm;
- (2) the accuracy of dose, dwell time and treatment time calculations at representative points;
- (3) the accuracy of isodose plots and graphic displays;
- (4) the accuracy of the software used to determine sealed source positions from radiographic images; and

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

[20.3.7.711 NMAC - Rp, 20 NMAC 3.1.7.710, 04/30/2009, A, XX/XX/2022]

This is an amendment to 20.3.7.712 NMAC, Sub-Section A effective XX/XX/2022.

20.3.7.712 SEALED SOURCES FOR DIAGNOSIS:

A. 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]~~ 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 U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

D[B]. Survey instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation survey meter capable of detecting dose rates ranging from 0.1 millirem (1 millisievert) per hour to 1000 millirems (10 millisieverts) per hour. The instrument shall be operable and calibrated in accordance with section Subsection C of 20.3.7.703 NMAC.

[20.3.7.712 NMAC - Rp, 20 NMAC 3.1.7.711, 04/30/2009,A,XX/XX/2022]

This is an amendment to 20.3.7.714 NMAC, Sub-Section A effective XX/XX/2022.

20.3.7.714 TRAINING REQUIREMENTS:

A. **Radiation safety officer and Associate Radiation Safety Officer.** The regulations of the NRC set forth in 10 CFR 35.50 are hereby incorporated by reference.

B. **Training for an authorized medical physicist.** The regulations of the NRC set forth in 10 CFR 35.51 are hereby incorporated by reference.

C. **Training for an authorized nuclear pharmacist.** The regulations of the NRC set forth in 10 CFR 35.55 are hereby incorporated by reference.

D. **Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist.** The regulations of the NRC set forth in 10 CFR 35.57 are hereby incorporated by reference.

E. **Recentness of training.** The training and experience specified in Subsections A, B, C, F, G, H, I, J, K, L, M, N and O of this section must have been obtained within the 7 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.

F. **Training for uptake, dilution, and excretion studies.** (For use of unsealed radioactive material under 20.3.7.704 NMAC) The regulations of the NRC set forth in 10 CFR 35.190 are hereby incorporated by reference.

G. **Training for imaging and localization studies.** (For use of unsealed radioactive material under 20.3.7.705 NMAC) The regulations of the NRC set forth in 10 CFR 35.290 are hereby incorporated by reference.

H. Training for use of unsealed radioactive material for which a written directive is required. (For use of unsealed radioactive material under 20.3.7.708 NMAC) The regulations of the NRC set forth in 10 CFR 35.390 are hereby incorporated by reference.

I. Training for the oral administration of sodium iodide i-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.392 are hereby incorporated by reference.

J. Training for the oral administration of sodium iodide i-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.394 are hereby incorporated by reference.

K. Training for the parenteral administration of unsealed byproduct material requiring a written directive. The regulations of the NRC set forth in 10 CFR 35.396 are hereby incorporated by reference.

L. Training for use of manual brachytherapy sources. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.490 are hereby incorporated by reference.

M. Training for ophthalmic use of strontium-90. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.491 are hereby incorporated by reference.

N. Training for use of sealed sources for diagnosis: (For use of radioactive material under 20.3.7.712 NMAC) The regulations of the NRC set forth in 10 CFR 35.590 are hereby incorporated by reference.

O. Training for use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units (For use of radioactive material under 20.3.7.711 NMAC). The regulations of the NRC set forth in 10 CFR 35.690 are hereby incorporated by reference.

P. Modifications. The following modifications are made to the incorporated federal regulations in this section.

- (1) "Commission" means the *department or NRC*.
- (2) "Act" means the *Radiation Protection Act*, Sections 74-3-1 through 74-3-16 NMSA

1978.

- (3) "Byproduct material" means *radioactive material* as defined in this chapter.
- (4) "10 CFR 35.100" means 20.3.7.704 NMAC.
- (5) "10 CFR 35.200" means 20.3.7.705 NMAC.
- (6) "10 CFR 35.300" means 20.3.7.708 NMAC.
- (7) "10 CFR 35.400" means 20.3.7.710 NMAC.
- (8) "10 CFR 35.500" means 20.3.7.712 NMAC.
- (9) "10 CFR 35.600" means 20.3.7.711 NMAC.
- (10) "At all other locations of use" in Subsection D of this section, incorporating 10 CFR

35.57 means *at all other locations of use in non-licensing state*, as defined in 20.3.1.7 NMAC.

[20.3.7.714 NMAC - Rp, 20 NMAC 3.1.7.712, XX/XX/2022]

This is an amendment to 20.3.7.716 NMAC, Sub-Section A, D effective XX/XX/2022.

20.3.7.716 REPORTS:

A. Report and notification of a medical event.

(1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct [~~radioactive~~] material or radiation from byproduct [~~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 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue or 50 rems (0.5 sievert) shallow dose equivalent to the skin; and:

(i) the total dose delivered differs from the prescribed dose by twenty percent or more;

(ii) the total dosage delivered differs from the prescribed dosage by twenty percent 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 percent or more;

(b) a dose that exceeds 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue, or 50 rems (0.5 sievert) shallow dose equivalent to the skin from any of the following:

[radioactive] material;
 by the wrong route of administration;
 research subject;
 treatment; or

- (i) an administration of a wrong radioactive drug containing byproduct
- (ii) an administration of a radioactive drug containing radioactive material
- (iii) an administration of a dose or dosage to the wrong individual or human
- (iv) an administration of a dose or dosage delivered by the wrong mode of
- (v) a leaking sealed source; and

(c) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rems (0.5 sievert) to an organ or tissue and fifty percent 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).

(d) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following: the wrong radionuclide; the wrong individual or human research subject; sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(2) 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.

(3) The licensee shall notify by telephone the department no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the department within 15 days after discovery of the medical event.

(a) The written report must include:

(i) the licensee's name;

(ii) the name of the prescribing physician;

(iii) a brief description of the event;

(iv) why the event occurred;

(v) the effect, if any, on the individual(s) who received the administration;

(vi) what actions, if any, have been taken or are planned to prevent

recurrence; and

(vii) certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) 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 24 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. 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 24 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 responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate 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.

(6) 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 responsible relatives or guardians.

(7) A licensee shall:

(a) annotate a copy of the report provided to the department with the:

(i) name of the individual who is the subject of the event; and

(ii) social security number or other identification number, if one has been

assigned, of the individual who is the subject of the event; and

(b) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

B. Report and notification of a dose to an embryo, fetus or a nursing child.

(1) A licensee shall report any dose to an embryo or fetus that is greater than 5 rems (50 millisieverts) 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 or fetus was specifically approved, in advance, by the authorized user.

(2) 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:

(a) is greater than 5 rems (50 millisieverts) total effective dose equivalent; or

(b) has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(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 Paragraphs (1) or (2) in this subsection.

(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 Paragraphs (1) or (2) in this subsection.

(a) The written report must include:

(i) the licensee's name;

(ii) the name of the prescribing physician;

(iii) a brief description of the event;

(iv) why the event occurred;

(v) the effect, if any, on the embryo, fetus or the nursing child;

(vi) what actions, if any, have been taken or are planned to prevent

recurrence; and

(vii) 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.

(b) 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.

(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 Paragraph (1) or (2) of this subsection, 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 this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. 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.

(6) A licensee shall:

(a) annotate a copy of the report provided to the NRC with the:

of the event; and (i) name of the pregnant individual or the nursing child who is the subject

(ii) 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

(b) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

C. Report of a leaking source. A licensee shall file a report within five days if a leak test required by Subsection F of 20.3.7.703 NMAC reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination. The report must be filed with the department and it 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.

D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations:

(1) The licensee shall notify by telephone the department and NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the department and NRC 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.

(2) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the department and appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 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 (1) of this section.

[20.3.7.716 NMAC - N, 04/30/2009, A, XX/XX/2022]