TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 3 RADIATION PROTECTION
PART 7 MEDICAL USE OF RADIONUCLIDES

20.3.7.1 ISSUING AGENCY: Environmental Improvement Board.
[20.3.7.1 NMAC - Rp, 20 NMAC 3.1.1.100, 04/30/2009]

20.3.7.2 SCOPE: This part contains the requirements and provisions for the medical use of radioactive materials and for issuance of specific licenses authorizing the medical use of radioactive material. These requirements and provisions provide for the radiation safety of workers, the general public, patients and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, other parts in this chapter. The requirements and provisions of 20.3.3 NMAC, 20.3.4 NMAC, 20.3.10 NMAC and 20.3.16 NMAC apply to applicants and licensees subject to this part unless specifically exempted. Other federal, state or local regulations may apply.
[20.3.7.2 NMAC - Rp, 20 NMAC 3.1.7.700, 04/30/2009]

20.3.7.3 STATUTORY AUTHORITY: Sections 74-1-9, 74-3-5 and 74-3-9 NMSA 1978.
[20.3.7.3 NMAC - Rp, 20 NMAC 3.1.1.102, 04/30/2009]

20.3.7.4 DURATION: Permanent.
[20.3.7.4 NMAC - Rp, 20 NMAC 3.1.1.103, 04/30/2009]

20.3.7.5 EFFECTIVE DATE: April 30, 2009, unless a later date is cited at the end of a section.
[20.3.7.5 NMAC - Rp, 20 NMAC 3.1.1.104, 04/30/2009]

20.3.7.6 OBJECTIVE: This part provides for the medical use and licensing of radioactive materials.
[20.3.7.6 NMAC - Rp, 20 NMAC 3.1.1.105, 04/30/2009]

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. **"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. **"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. **"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. **“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. **“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. **“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. **"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. **“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. **“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. **“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 2 grays (200 rads) per hour at the point or surface where the dose is prescribed.

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

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

Q. **“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. **“Medium dose-rate remote afterloader”**, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 grays (200 rads) per hour, but less than or equal to12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

S. **“Mobile medical service”** means the transportation of radioactive material to and its medical use at the client's address.

T. **“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.

U. **"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. **"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. **"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. **"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. **"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. "**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. **"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 radiation safety officer.

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

HH. **"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. **"Temporary job site"** means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

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

MM. **"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. **"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. **"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]

20.3.7.8 - 20.3.7.699 [RESERVED]

20.3.7.700 GENERAL REGULATORY REQUIREMENTS:

A. Provisions for Research Involving Human Subjects.

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

(2) If the research is conducted, funded, supported or regulated by a federal agency that has implemented the *federal policy for the protection of human subjects* (45 CFR Part 46), the licensee shall, before conducting research:

(a) obtain review and approval of the research from an "institutional review board," as defined and described in the *federal policy for the protection of human subjects*; and

(b) obtain "informed consent," as defined and described in the *federal policy for the protection of human subjects*, from the human research subject.

(3) If the research will not be conducted, funded, supported or regulated by a federal agency that has implemented the *federal policy for the protection of human subjects*, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license issued by the department. The amendment request must include a written commitment that the licensee will, before conducting research:

(a) obtain review and approval of the research from an "institutional review board," as defined and described in the *federal policy for the protection of human subjects*; and

(b) obtain "informed consent," as defined and described in the *federal policy for the protection of human subjects*, from the human research subject.

(4) Nothing in this subsection relieves licensees from complying with the other requirements in this part.

B. FDA, Federal and State Requirements. Nothing in this part relieves the licensee from complying with applicable FDA, other federal and state requirements governing radioactive drugs or devices.

C. Implementation.

(1) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(2) A licensee shall continue to comply with any license condition that requires it to implement procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC until there is a license amendment or renewal that modifies the license condition.

D. License Required.

(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 or as allowed in Paragraph (2) of this subsection.

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

(a) receives, possesses, uses or transfers radioactive material in accordance with the requirements in this chapter under the supervision of an authorized user as provided in Subsection F of 20.3.7.702 NMAC unless prohibited by license condition; or

(b) prepares unsealed radioactive material for medical use in accordance with the requirements in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in Subsection F of 20.3.7.702 NMAC unless prohibited by license condition.

E. Application for License, Amendment or Renewal.

(1) An application must be signed by the applicant or licensee, or a person duly authorized to act for or on their behalf.

(2) An application for a license for medical use of radioactive material as described in 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 must be made by:

(a) filing in duplicate of a department form, *application for radioactive material license*, completed according to the instructions in the form; and

(b) submitting written procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable.

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

(a) filing in duplicate of a department form, *application for radioactive material license*, as described in Paragraph (2) of this subsection; and

(b) submitting procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable.

(4) In addition to the requirements in Paragraphs (2) and (3) of this subsection, an application for a license or amendment for medical use of radioactive material described in 20.3.7.713 NMAC must also include information regarding any radiation safety aspects of the medical use of the material that are not addressed in sections 20.3.7.702 NMAC and 20.3.7.703 NMAC. The applicant shall also provide specific information on:

(a) radiation safety precautions and instructions;

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

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

(5) The applicant or licensee shall also provide any other additional information requested by the department in its review of the application, license renewal or amendment, within 30 days of the request or other time as may be specified in the request.

(6) An applicant that satisfies the requirements specified in Subsection B of 20.3.3.314 NMAC may apply for a type "A" specific license of broad scope.

F. License Amendments. A licensee shall apply for and must receive a license amendment:

(1) before it receives, prepares or uses radioactive material for a type of use that is permitted under 20.3.7 NMAC but that is not authorized on the licensee's current license issued under this part;

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

(a) for an authorized user, an individual who meets the definition of an *authorized user* as defined in 20.3.7.7 NMAC;

(b) for an authorized nuclear pharmacist, an individual who meets the definition of an *authorized nuclear pharmacist* as defined in 20.3.7.7 NMAC;

(c) for an authorized medical physicist, an individual who meets the definition of an *authorized medical physicist* as defined in 20.3.7.7 NMAC; or

(d) a physician, podiatrist or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials 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 in non-licensing state (as defined in 20.3.1.7 NMAC) before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates;

(3) before it changes radiation safety officers, except as provided in Paragraph (4) of Subsection A of 20.3.7.702 NMAC;

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

(5) before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC if the change includes the addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; other areas of use where radioactive material is used only in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC are exempt;

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

(7) before it revises procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable, where such revision reduces radiation safety.

G. Notifications.

(1) For each individual, no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under Paragraph (2) of Subsection F of this section: *1)* the licensee shall verify the training and experience and provide the department with a copy the documentation demonstrating the training and experience as listed in the definitions of authorized user, authorized nuclear pharmacist or authorized medical physicist in 20.3.7.7 NMAC; or *2)* the licensee shall verify the training and experience and provide the department of a copy of the documentation demonstrating that only accelerator-produced radioactive materials, discrete sources, or both, were used for medical use 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 in non-licensing states (as defined in 20.3.1.7 NMAC) before August 8, 2009, or an earlier date as noticed by the NRC.

(2) A licensee shall notify the department by letter no later than 30 days after:

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

(b) the licensee permits an authorized user or an individual qualified to be a radiation safety officer, under Subsection A of 20.3.7.714 NMAC, incorporating 10 CFR 35.50 and Subsection 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 in accordance with Paragraph (4) of Subsection A of 20.3.7.702 NMAC.

(c) the licensee's mailing address changes;

(d) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Subsection B of 20.3.3.317 NMAC; or

(e) the licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area.

(3) A licensee shall notify the department by letter no later than 30 days after a calibration, transmission or reference source under Subsection E of 20.3.7.703 NMAC is acquired. The notification shall contain a description of the source, manufacturer name, model and serial number of the source, and the license number of the manufacturer of the specific license issued by the department, NRC or an agreement state under Subsection K of 20.3.3.315 NMAC or equivalent NRC or agreement state requirements.

(4) The licensee shall send the documents required in this subsection to the appropriate address identified in 20.3.1.116 NMAC.

H. Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a type "A" specific license of broad scope for medical use, issued under 20.3.3.314 NMAC, is exempt from:

(1) the provisions of Paragraph 4 of Subsection E of 20.3.7.700 NMAC regarding the need to file an amendment to the license for medical use of radioactive materials, for use described in 20.3.7.713 NMAC;

(2) the provisions of Paragraph (2) of Subsection F of 20.3.7.700 NMAC;

(3) the provisions of Paragraph (5) of Subsection F of 20.3.7.700 NMAC regarding additions to or changes in the areas of use at the addresses specified in the application or on the license;

(4) the provisions of Paragraph (1) of Subsection G of 20.3.7.700 NMAC;

(5) the provisions of Subparagraph (a) of Paragraph (2) of Subsection G of 20.3.7.700 NMAC for an authorized user, an authorized nuclear pharmacist or an authorized medical physicist;

(6) the provisions of Subparagraph (e) of Paragraph (2) of Subsection G of 20.3.7.700 NMAC regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC;

(7) the provisions in Paragraph (3) of Subsection G of 20.3.7.700 NMAC; and

(8) the provisions of Paragraph (1) of Subsection I of 20.3.7.702 NMAC.

[20.3.7.700 NMAC - Rp, 20 NMAC 3.1.7.700, 04/30/2009]

20.3.7.701 [RESERVED]

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.

(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 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 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 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).

(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.

(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]

20.3.7.703 GENERAL TECHNICAL REQUIREMENTS:

A. Possession, Use and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material. Other than unit dosages of beta-emitting unsealed radioactive material obtained from the manufacturer or preparer, licensed pursuant to Subsection J of 20.3.3.315 NMAC, a medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator, and use it to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject.

(1) A licensee shall:

(a) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use; to satisfy the requirements of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kilobecquerels) of radium-226 or 50 microcuries (1.85 megabecquerels) of any other photon-emitting radionuclide;

(b) test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kilobecquerels) for radium-226 and 50 microcuries (1.85 megabecquerels) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 kiloelectron volts and 500 kiloelectron volts;

(c) test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 30 microcuries (1.11 megabecquerels), and the highest dosage that will be administered to a patient or human research subject; and

(d) test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used; the licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(2) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kilobecquerels), and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(3) A licensee shall also perform checks and tests required under this subsection, following adjustment or repair of the dose calibrator.

(4) Beta-emitting radionuclides. A licensee shall develop quality control procedures and use appropriate instrumentation to measure the radioactivity for beta-emitting radiopharmaceuticals. A licensee may use checks, tests or calibration techniques other than those described in this section for instruments measuring the dosages of beta-emitting unsealed radioactive material if checks, tests or calibration techniques are in accordance with nationally recognized standards or the equipment manufacturer's instructions and have been approved by the department.

(5) A licensee shall retain a record of each instrument check, test and calibration required by this subsection in accordance with Subsection E of 20.3.7.715 NMAC.

B. Determination of Dosages of Unsealed Radioactive Material for Medical Use.

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

(2) This determination must be made by:

(a) direct measurement of radioactivity pursuant to Subsection A of this section;

(b) combination of direct measurement of radioactivity pursuant to Subsection A of this section and mathematical calculations;

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

(i) a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC or equivalent requirement of NRC or agreement state; or

(ii) a PET radioactive drug producer licensed under Subsection J of 20.3.3.307 NMAC or equivalent NRC or agreement state requirements; or

(d) decay correction, for unit dosages of beta-emitting unsealed radioactive material, based on the activity or activity concentration determined by:

(i) a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC or equivalent NRC or agreement state requirement;

(ii) 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 (IND) protocol accepted by FDA; or

(iii) a PET radioactive drug producer licensed under Subsection J of 20.3.3.307 NMAC or equivalent NRC or agreement state requirements.

(3) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(4) A licensee shall retain a record of the dosage determination required by this subsection in accordance with Subsection G of 20.3.7.715 NMAC.

C. Calibration and Check of Radiation Survey Instruments.

(1) A licensee shall calibrate the radiation survey instruments used to show compliance with this part and 20.3.4 NMAC before first use, annually and following a repair that affects the calibration.

(2) A licensee shall:

(a) calibrate all scales with readings up to 1000 millirems (10 millisieverts) per hour with a radiation source;

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

(c) conspicuously note on the instrument the date of calibration.

(3) A licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by no more than 20 percent.

(4) A licensee shall check each radiation survey instrument for proper operation with a dedicated check source at the beginning of each day of use.

(5) A licensee shall retain a record of each radiation survey instrument calibration in accordance with Subsection F of 20.3.7.715 NMAC.

D. Quality Control for Other Equipment. Each licensee shall establish written quality control procedures (checks, tests, calibrations, efficiency measurements, etc.) for equipment used to obtain quantitative radiation measurements for radionuclide studies, described in this part, or radiation safety surveys, necessary to demonstrate compliance with this part and 20.3.4 NMAC. At a minimum, quality control procedures and their frequencies shall be those recommended by the equipment manufacturer.

E. Authorization for Calibration, Transmission and Reference Sources. Any person authorized by Subsection D of 20.3.7.700 NMAC for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

(1) sealed sources, not exceeding 30 millicuries (1.11 gigabecquerels) each, manufactured and distributed by a person specifically licensed under Subsection K of 20.3.3.315 NMAC or equivalent NRC or an agreement state requirements;

(2) sealed sources, not exceeding 30 millicuries (1.11 gigabecquerels) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Subsection K of 20.3.3.315 NMAC, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) any radioactive material with a half-life no longer than 120 days in individual amounts not to exceed 15 millicuries (0.56 gigabecquerel);

(4) any radioactive material with a half-life longer than 120 days in individual amounts not to exceed 200 microcuries (7.4 megabecquerels) or 1000 times the quantities in 20.3.3.338 NMAC; and

(5) technetium-99m in amounts as needed but not to exceed 100 millicuries.

F. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer and shall maintain the instructions for the duration of source use in a legible form convenient for users.

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

(a) test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(b) test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the department, NRC or an agreement state.

(3) To satisfy the leak test requirements of this subsection, the licensee shall measure the sample so that the leak test can detect the presence of 0.005 microcurie (185 becquerels) of radioactive material in the sample.

(4) A licensee shall retain leak test records in accordance with Paragraph (1) of Subsection H of 20.3.7.715 NMAC.

(5) If the leak test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, the licensee shall:

(a) immediately withdraw the sealed source from use and store, cause it to be repaired or disposed of in accordance with the requirements in 20.3.3 NMAC and 20.3.4 NMAC; and

(b) file a report within 5 days of the leak test result in accordance with Subsection C of 20.3.7.716 NMAC.

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

(a) sources containing only radioactive material with a half-life of less than 30 days;

(b) sources containing only radioactive material as a gas;

(c) sources containing 100 microcuries (3.7 megabecquerels) or less of beta or gamma-emitting material or 10 microcuries (0.37 megabecquerel) or less of alpha-emitting material;

(d) seeds of iridium-192 encased in nylon ribbon; and

(e) sources stored and not being used; however, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months, or other frequency approved by the department, NRC or an agreement state, before the date of use or transfer.

(7) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with Paragraph (2) of Subsection H of 20.3.7.715 NMAC.

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

H. Surveys for Contamination and Ambient Radiation Exposure Rate.

(1) In addition to the surveys required by 20.3.4 NMAC:

(a) a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared or administered; and

(b) a licensee shall survey for removable contamination at the end of each day of use all areas where radiopharmaceuticals requiring written directive are routinely prepared for use or administered.

(2) A licensee does not need to perform the surveys required by Paragraph (1) of this subsection in areas where patients or human research subjects are confined when they cannot be released under Subsection I of 20.3.7.703 NMAC.

(3) A licensee shall retain a record of each survey in accordance with Subsection I of 20.3.7.715 NMAC.

I. Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

(1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 millisieverts) (the current revision of the NRC guidance NUREG-1556, volume 9, "*consolidated guidance about materials licenses: program-specific guidance about medical licenses*", describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 millisieverts)).

(2) A licensee shall provide the released individual or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 millisievert). If the total effective dose equivalent to a nursing infant or child could exceed 0.1 rem (1 millisievert), assuming there was no interruption of breast-feeding, the instructions must also include:

(a) guidance on the interruption or discontinuation of breast-feeding; and

(b) information on the potential consequences, if any, of failure to follow the guidance.

(3) A licensee shall maintain a record of the basis for authorizing the release of an individual, in accordance with Paragraph (1) of Subsection J of 20.3.7.715 NMAC.

(4) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with Paragraph (2) of Subsection J of 20.3.7.715 NMAC.

J. Provision of Mobile Medical Service.

(1) A licensee providing mobile medical service shall:

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

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

(c) check radiation survey instruments for proper operation with a dedicated check source before use at each client's address or on each day of use, whichever is more frequent; and

(d) before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 20.3.4 NMAC and 20.3.7 NMAC.

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

(3) A licensee providing mobile medical services shall retain the letter required in Subparagraph (a) of Paragraph (1) of this subsection and the record of each survey required in Subparagraph (d) of Paragraph (1) of this subsection in accordance with Paragraphs (1) and (2) of Subsection K of 20.3.7.715 NMAC, respectively.

K. Storage of Volatiles and Gases.

(1) A license shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container.

(2) A license shall store and use a multi-dosage container in a properly functioning fume hood.

L. Decay-in-Storage.

(1) A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard of its radioactivity if the licensee:

(a) holds radioactive material for decay a minimum of 10 half-lives;

(b) monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(c) removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

(d) separates and monitors each generator column individually with all radiation shielding removed to ensure that its content have decayed to background radiation level before disposal.

(2) A licensee shall retain a record of each disposal permitted under Paragraph (1) of this subsection in accordance with Subsection L of 20.3.7.715 NMAC.

[20.3.7.703 NMAC - Rp, 20 NMAC 3.1.7.703, 04/30/2009]

20.3.7.704 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: Except for quantities that require a written directive under Paragraph (3) of Subsection G of Section 20.3.7.702 NMAC, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution or excretion studies that is:

A. obtained from:

(1) a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC, or equivalent NRC or agreement state requirements; or

(2) a PET radioactive drug producer licensed under Subsection J of 20.3.3.307 NMAC or equivalent NRC or agreement state requirements; or

B. excluding production of PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in 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, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290(c)(1)(ii)(G); 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 drug protocol accepted by FDA.

[20.3.7.704 NMAC - Rp, 20 NMAC 3.1.7.704, 04/30/2009]

20.3.7.705 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: Except for quantities that require a written directive under Paragraph (3) of Subsection G of 20.3.7.702 NMAC, a licensee may use any unsealed radioactive material prepared for medical for imaging and localization studies use that is:

A. obtained from:

(1) a manufacturer or preparer licensed pursuant to Subsection J of 20.3.3.315 NMAC or equivalent NRC or agreement state requirements; or

(2) a PET radioactive drug producer licensed under Subsection J of 20.3.3.307 NMAC or equivalent NRC or agreement state requirements; or

B. excluding production of PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in 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, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290(c)(1)(ii)(G); 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 drug protocol accepted by FDA.

[20.3.7.705 NMAC - Rp, 20 NMAC 3.1.7.705, 04/30/2009]

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.

(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.

[20.3.7.706 NMAC - Rp, 20 NMAC 3.1.7.706, xx/xx/06]

20.3.7.707 CONTROL OF AEROSOLS AND GASES:

A. System Requirements.

(1) A licensee who administers radioactive aerosols or gases shall do so with a system that shall keep airborne concentrations of the radioactive material, including releases to the environment, within the limits prescribed by 20.3.4 NMAC.

(2) The delivery or control system for the radioactive aerosols or gases shall either be directly vented to the atmosphere though an air exhaust or shall provide collection and decay or disposal of the aerosol or gas in a shielded container. Other federal, state or local regulatory requirements shall be met.

(3) The licensee shall perform check of the operation of reusable gas collection systems monthly or at other frequency approved by the department.

B. Room Requirements.

(1) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(2) The licensee shall perform measurements of ventilation rate at least semiannually or other frequency approved by the department for those areas of use required to operate under a negative pressure.

C. Clearance Time.

(1) Before receiving, using or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the limits in 20.3.4.461 NMAC. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(2) A licensee shall post the time calculated in Paragraph (1) of this subsection in the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed or the concentration in the area of use is reduced below the limits in 20.3.4.461 NMAC.

D. Record keeping. A copy of the calculations required in Paragraph (1) of Subsection C of this section shall be retained in accordance with Subsection N of 20.3.7.715 NMAC.

[20.3.7.707 NMAC - Rp, 20 NMAC 3.1.7.707, 04/30/2009]

20.3.7.708 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is 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]

20.3.7.709 SAFETY INSTRUCTIONS AND PRECAUTIONS FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: In addition to the requirements in 20.3.10.1002 NMAC, the licensee shall provide the following.

A. Safety Instructions. A licensee shall provide radiation safety instructions initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under Subsection I of 20.3.7.703 NMAC. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) patient or human research subject control;

(2) visitor control, including:

(a) routine visitation to hospitalized individuals in accordance with Paragraph (1) of Subsection A of 20.3.4.413 NMAC; and

(b) visitation authorized in accordance with Subsection F of 20.3.4.413 NMAC;

(3) contamination control;

(4) waste control; and

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

B. Record Keeping. A licensee shall retain a record of individuals receiving safety instructions, as specified in Subsection A of this section, in accordance with Subsection O of 20.3.7.715 NMAC.

C. Safety Precautions. For each patient or human research subject who cannot be released under Subsection I of 20.3.7.703 NMAC, a licensee shall:

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

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

(b) a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under Subsection I of 20.3.7.703 NMAC;

(2) visibly post the patient's or human research subject's room with a “Radioactive Materials” sign;

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

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

(5) 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.

[20.3.7.709 NMAC - Rp, 20 NMAC 3.1.7.708, 04/30/2009]

20.3.7.710 MANUAL BRACHYTHERAPY:

A. Use of Sources for Manual Brachytherapy. 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 1 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.

(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]

20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY 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) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

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

(b) the operating procedures for the unit.

(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.

(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.

(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 2 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 5 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 1 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 3 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 1 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 5 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 1 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 5 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 3 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 1 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.

(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]

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*.

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]

20.3.7.713 OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL: A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in 20.3.7.704 NMAC through 20.3.7.712 NMAC of this part if:

A. the applicant or licensee has submitted the information required by Paragraph (2) through (4) of Subsection E of 20.3.7.700 NMAC; and

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

[20.3.7.713 NMAC - N, 04/30/2009]

20.3.7.714 TRAINING REQUIREMENTS:

A. 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, 04/30/2009]

20.3.7.715 RECORDS:

A. Records of Authority and Responsibilities for Radiation Protection Programs.

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with Subsection C of 20.3.7.702 NMAC for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(2) The licensee shall retain a copy of both authority, duties and responsibilities of the radiation safety officer as required by Paragraph (2) of Subsection A of 20.3.7.702 NMAC, and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by Paragraph (1) of Subsection A of 20.3.7.702 NMAC, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

B. Records of Radiation Protection Program Changes. A licensee shall retain a record of each radiation protection program change made in accordance with Subsection E of 20.3.7.702 NMAC for 5 years. The record must include a copy of the old and new procedures, the effective date of the change and the signature of the licensee management that reviewed and approved the change.

C. Records of Written Directives. A licensee shall retain a copy of each written directive as required by Subsection G of 20.3.7.702 NMAC for 3 years.

D. Records for Procedures for Administrations Requiring a Written Directive. A licensee shall retain a copy of the procedures required by Subsection H of 20.3.7.702 NMAC for the duration of the license.

E. Records of Calibrations, Test or Checks of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument checks, tests and calibrations required by Subsection A of 20.3.7.703 NMAC for 3 years. The records must include the model and serial number of the instrument, the date of the check, test or calibration, the activity and serial number of the calibration source(s) used for the check, test or calibration, whichever applicable, the results of the check, test or calibration and the name of the individual who performed the check, test or calibration.

F. Records of Radiation Survey Instrument Calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by Subsection C of 20.3.7.703 NMAC for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration and the name of the individual who performed the calibration.

G. Records of Dosages of Unsealed Radioactive Material for Medical Use.

(1) A licensee shall maintain a record of dosage determinations required by Subsection B of 20.3.7.703 NMAC for 3 years.

(2) The record must contain:

(a) the radiopharmaceutical;

(b) the patient's or human research subject's name or identification number if one has been assigned;

(c) the prescribed dosage, the determined dosage or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

(d) the date and time of the dosage determination; and

(e) the name of the individual who determined the dosage.

H. Records of Leaks Tests and Inventory of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain records of leak tests required by Paragraph (2) of Subsection F of 20.3.7.703 NMAC for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test and the name of the individual who performed the test.

(2) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Paragraph (7) of Subsection F of 20.3.7.703 NMAC for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source and the name of the individual who performed the inventory.

I. Records of Surveys. A licensee shall retain a record of each survey required by Subsection H of 20.3.7.703 NMAC for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the individual who performed the survey.

J. Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(1) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with Subsection I of 20.3.7.703 NMAC, if the total effective dose equivalent is calculated by:

(a) using the retained activity rather than the activity administered;

(b) using an occupancy factor less than 0.25 at 1 meter;

(c) using the biological or effective half-life; or

(d) considering the shielding by tissue.

(2) A licensee shall retain a record that the instructions required by Paragraph (2) of Subsection I of 20.3.7.703 NMAC were provided to a breast-feeding female if the radiation dose to the infant or child from continued breastfeeding could result in a total effective dose equivalent exceeding 0.5 rem (5 millisieverts).

(3) The records required by Paragraphs (1) and (2) of this section must be retained for 3 years after the date of release of the individual.

K. Records of Mobile Medical Services.

(1) A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by Subparagraph (a) of Paragraph (1) of Subsection J of 20.3.7.703 NMAC. Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(2) A licensee shall retain the record of each survey required by Subparagraph (d) of Paragraph (1) of Subsection J of 20.3.7.703 NMAC for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the individual who performed the survey.

L. Records of Decay-In-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by Subsection L of 20.3.7.703 NMAC, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container and the name of the individual who performed the survey.

M. Records of Molybdenum-99, Strontium-82 and Strontium-85 Concentrations. A licensee shall maintain a record of the molybdenum-99, strontium-82 and strontium-85 concentration tests required by 20.3.7.706 NMAC for 3 years. The record must include:

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

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

N. Records of Gas Controls. A licensee shall maintain the records specified in Subsection D of 20.3.7.707 NMAC for 3 years.

O. Records of Safety Instructions. A licensee shall maintain a record of safety instructions required by Subsection A of 20.3.7.709 NMAC, Subsection D of 20.3.7.710 NMAC and Subsection D of 20.3.7.711 NMAC for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s) and the name(s) of the individual(s) who provided the instruction.

P. Records of Surveys after Source Implant and Removal. A licensee shall maintain a record of the surveys required by Subsection B of 20.3.7.710 NMAC and Subsection B of 20.3.7.711 NMAC for 3 years. Each record must include the date and results of the survey, the survey instrument used and the name of the individual who made the survey.

Q. Records of Brachytherapy Source Accountability.

(1) A licensee shall maintain a record of brachytherapy source accountability required by Subsection B of 20.3.7.710 NMAC for 3 years.

(2) For temporary implants, the record must include:

(a) the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage and the location of use; and

(b) the number and activity of sources returned to storage, the time and date they were returned to storage and the name of the individual who returned them to storage.

(3) For permanent implants, the record must include:

(a) the number and activity of sources removed from storage, the date they were removed from storage and the name of the individual who removed them from storage;

(b) the number and activity of sources not implanted, the date they were returned to storage and the name of the individual who returned them to storage; and

(c) the number and activity of sources permanently implanted in the patient or human research subject.

R. Records of Calibration Measurements of Brachytherapy Sources.

(1) A licensee shall maintain a record of the calibrations of brachytherapy sources required by Subsection F of 20.3.7.710 NMAC for 3 years after the last use of the source.

(2) The record must include:

(a) the date of the calibration;

(b) the manufacturer's name, model number and serial number for the source and the instruments used to calibrate the source;

(c) the source output or activity;

(d) the source positioning accuracy within the applicators; and

(e) the name of the individual, the source manufacturer or the calibration laboratory that performed the calibration.

S. Records of Decay of Strontium- 90 Sources for Ophthalmic Treatments.

(1) A licensee shall maintain a record of the activity of a strontium-90 source required by Subsection G of 20.3.7.710 NMAC for the life of the source.

(2) The record must include:

(a) the date and initial activity of the source as determined under Subsection F of 20.3.7.710 NMAC; and

(b) for each decay calculation, the date and the source activity as determined under Subsection G of 20.3.7.710 NMAC.

T. Records of Installation, Maintenance, Adjustment and Repair of Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units. A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units as required by Subsection C of 20.3.7.711 NMAC for 3 years. For each installation,

maintenance, adjustment and repair, the record must include the date, description of the service and name(s) of the individual(s) who performed the work.

U. Records of Safety Procedures. A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) of Subsection D of 20.3.7.711 NMAC and Subparagraph (b) of Paragraph (4) of Subsection D of 20.3.7.711 NMAC until the licensee no longer possesses the remote afterloader, teletherapy unit or gamma stereotactic radiosurgery unit.

V. Records of Dosimetry Equipment Used with Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of the calibration, inter-comparison and comparisons of its dosimetry equipment done in accordance with Subsection F of 20.3.7.711 NMAC for the duration of the license.

(2) For each calibration, inter-comparison or comparison, the record must include:

(a) the date;

(b) the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared or compared as required by Paragraphs (1) and (2) of Subsection F of 20.3.7.711 NMAC;

(c) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and

(d) the names of the individuals who performed the calibration, inter-comparison or comparison.

W. Records of Teletherapy, Remote Afterloader and Gamma Stereotactic Radiosurgery Full Calibrations.

(1) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit and gamma stereotactic radiosurgery unit full calibrations required by Subsection G of 20.3.7.711 NMAC, Subsection H of 20.3.7.711 NMAC and Subsection I of 20.3.7.711 NMAC for 3 years, respectively.

(2) The record must include:

(a) the date of the calibration;

(b) the manufacturer's name, model number and serial number of the teletherapy, remote afterloader and gamma stereotactic radiosurgery unit(s), the source(s) and the instruments used to calibrate the unit(s);

(c) the results and an assessment of the full calibrations;

(d) the results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) the signature of the authorized medical physicist who performed the full calibration.

X. Records of Periodic Spot Checks for Teletherapy Units.

(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Subsection J of 20.3.7.711 NMAC for 3 years.

(2) The record must include:

(a) the date of the spot-check;

(b) the manufacturer's name, model number and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(c) an assessment of timer linearity and constancy;

(d) the calculated on-off error;

(e) a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(f) the determined accuracy of each distance measuring and localization device;

(g) the difference between the anticipated output and the measured output;

(h) 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

(i) 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.

(3) A licensee shall retain a copy of the procedures required by Paragraph (2) of Subsection J of 20.3.7.711 NMAC until the licensee no longer possesses the teletherapy unit.

Y. Records of Periodic Spot-checks for Remote Afterloader Units.

(1) A licensee shall retain a record of each spot-check for remote afterloader units required by Subsection K of 20.3.7.711 NMAC for 3 years.

(2) The record must include, as applicable:

(a) the date of the spot-check;

(b) the manufacturer's name, model number and serial number for the remote afterloader unit and source;

(c) an assessment of timer accuracy;

(d) notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems and clock and decayed source activity in the unit's computer; and

(e) 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.

(3) A licensee shall retain a copy of the procedures required by Paragraph (2) of Subsection K of 20.3.7.711 NMAC until the licensee no longer possesses the remote afterloader unit.

Z. Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Subsection L of 20.3.7.711 NMAC for 3 years.

(2) The record must include:

(a) the date of the spot-check;

(b) the manufacturer's name, model number and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(c) an assessment of timer linearity and accuracy;

(d) the calculated on-off error;

(e) a determination of trunnion centricity;

(f) the difference between the anticipated output and the measured output;

(g) an assessment of source output against computer calculations;

(h) notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism and stereotactic frames and localizing devices (trunnions); and

(i) 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.

(3) A licensee shall retain a copy of the procedures required by Paragraph (2) of Subsection L of 20.3.7.711 NMAC until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

AA. Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(1) A licensee shall retain a record of each check for mobile remote afterloader units required by Subsection M of 20.3.7.711 NMAC for 3 years.

(2) The record must include:

(a) the date of the check;

(b) the manufacturer's name, model number and serial number of the remote afterloader unit;

(c) notations accounting for all sources before the licensee departs from a facility;

(d) notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes and transfer tube applicator interfaces and source positioning accuracy; and

(e) the signature of the individual who performed the check.

BB. Records of Surveys of Therapeutic Treatment Units.

(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Subsection N of 20.3.7.711 NMAC for the duration of use of the unit.

(2) The record must include:

(a) the date of the measurements;

(b) the manufacturer's name, model number and serial number of the treatment unit, source and instrument used to measure radiation levels;

(c) each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) the signature of the individual who performed the test.

CC. Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Subsection O of 20.3.7.711 NMAC for the duration of use of the unit.

(2) The record must contain:

(a) the inspector's radioactive materials license number;

(b) the date of inspection;

(c) the manufacturer's name, model number and serial number of both the treatment unit and source;

(d) a list of components inspected and serviced and the type of service; and

(e) the signature of the inspector.

[20.3.7.715 NMAC - N, 04/30/2009]

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 radioactive material or radiation from radioactive material 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 20 percent or more;

(ii) the total dosage delivered differs from the prescribed dosage by 20 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 50 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:

(i) an administration of a wrong radioactive drug containing radioactive material;

(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) an administration of a dose or dosage to the wrong individual or human research subject;

(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) a leaking sealed source; 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 50 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).

(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:

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

(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 5 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.

[20.3.7.716 NMAC - N, 04/30/2009]

HISTORY OF 20.3.7 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the commission of public records - state records center and archives.

EIB 73-2, Regulations for Governing the Health and Environmental Aspects of Radiation filed 7-9-73; EIB 73-2, Amendment 1, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 4-17-78; EIB RPR-1, Radiation Protection Regulations filed on 4-21-80; EIB RPR-1, Amendment 1, Radiation Protection Regulations filed on 10-13-81; EIB RPR-1, Amendment 2, Radiation Protection Regulations filed on 12-15-82; and EIB RPR-1, Radiation Protection Regulations filed on 3-10-89.

History of Repealed Material: 20 NMAC 3.1.Subpart 7, Medical Use Of Radionuclides (filed 06-17-1999) repealed 04/30/2009.

Other History: EIB RPR 1, Radiation Protection Regulations (filed 03-10-1989) was renumbered and reformatted to 20 NMAC 3.1, Radiation Materials And Radiation Machines, effective 05-03-1995.

20 NMAC 3.1, Radiation Materials And Radiation Machines (filed 04-03-1995) was internally renumbered, reformatted and replaced by 20 NMAC 3.1, Radiation Materials And Radiation Machines, effective 07-30-1999.

20 NMAC 3.1.Subpart 7, Medical Use Of Radionuclides (filed 06-17-1999) was reformatted, renumbered and replaced by 20.3.7 NMAC, Medical Use Of Radionuclides, effective 04/30/2009.