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TITLE 180 CONTROL OF RADIATION

CHAPTER 7 MEDICAL USE OF RADIOACTIVE MATERIAL

GENERAL INFORMATION

7-001 SCOPE AND AUTHORITY: 180 NAC 7 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of 180 NAC 7 are in addition to, and not in substitution for, others in Title 180. The requirements and provisions of 180 NAC 1, 3, 4, 10, 13, 15, 17, and 18 apply to applicants and licensees subject to 180 NAC 7 unless specifically exempted. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

7-002 DEFINITIONS: As used in 180 NAC 7, the following definitions apply:

Accredited institution means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

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

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

Authorized medical physicist means an individual who:

1. Meets the requirements in 180 NAC 7-023.01 and 7-027; or
2. Is identified as an authorized medical physicist or teletherapy physicist on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized medical physicist on a permit issued by an Department, Nuclear Regulatory Commission or Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized nuclear pharmacist means a pharmacist who:

1. Meets the requirements of 180 NAC 7-024.01 and 7-027; or
2. Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial

nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Department, Nuclear Regulatory Commission or Agreement State; or

3. Is identified as an authorized nuclear pharmacist on a permit issued by the Department, Nuclear Regulatory Commission or Agreement State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized user means a physician, dentist, or podiatrist who:

1. Meets the requirements in 180 NAC 7-027 and 7-043.01, 7-047.01, 7-052.01, 7-053.01, 7-054.01, 7-063.01, 7-066.01 or 7-084.01; or
2. Is identified as an authorized user on a specific license or equivalent permit issued by the Department, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized user on a permit issued by an Department, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.

Brachytherapy means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

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.

Client's address means the address of use or a temporary job site for the purpose of providing mobile medical service in accordance with 180 NAC 7-038.

Dedicated check source means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

High dose-rate remote afterloader (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low dose-rate remote afterloader (LDR), means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

Management means the individual having the authority to manage, direct, or administer the licensee's activities, or that persons' designee(s).

Manual brachytherapy means a type of therapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually applied or inserted.

Medical institution means an organization in which several medical disciplines are practiced.

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.

Medium dose-rate remote afterloader (MDR) means a brachytherapy device that remotely delivers a dose rate of greater that 2 gray (200 rads) per hour, but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Misadministration means an event that meets the criteria in 180 NAC 7-115.

Mobile medicine service means the transportation of radioactive material and\or its medical use at the client's address.

Nuclear medicine technologist means an individual who meets the requirements of 180 NAC 7-025.01 and is under the supervision of an authorized user, to prepare or administer radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.

Nuclear medicine technology means the science and art of *in vivo* or *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.

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.

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.

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, a nuclear medicine technologist, a radiation therapy technologist or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of radioactive drug as documented:

1. In a written directive as specified in 180 NAC 7-019; or
2. In accordance with the directions of the authorized user for procedures performed per 180 NAC 7-041, 7-044 and 7-048.

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.

Pulsed dose-rate remote afterloader (PDR) means a special type of remote afterloading 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.

Radiation Safety Officer (RSO) means an individual who:

1. Meets the requirements in 180 NAC 7-022.01 and 7-026;
2. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Department for similar types and uses of radioactive material.

Radiation therapist means an individual who meets the requirements of 180 NAC 7-025.02 and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

Radiation therapy technology means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

Radioactive drug means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

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

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

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

Teletherapy means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

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

Therapeutic dosage means a radiation 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.

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.

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

Type of use means use of radioactive material as specified in 180 NAC 7-041, 7-044, 7-048, 7-055, 7-065, 7-067 or 7-085.

Unit dosage means a dosage that:

1. Is obtained or prepared in accordance with the regulations for uses described in 180 NAC 7-041, 7-044, or 7-048; and
2. Is to be administered as a single dosage to patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of a radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 180 NAC 7-019.

7-003 MAINTENANCE OF RECORDS: Each record required by this 180 NAC 7 must be legible throughout the retention period specified by Title180. The record may be the original, a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

7-004 PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS: A licensee may conduct research involving human subjects using radioactive material provided:

7-004.01 That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee may apply for and receive approval of a specific amendment to its Department license before conducting such research. Both types of licensees must, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

7-004.02 The research involving human subjects authorized in 180 NAC 7-004.01 maybe conducted using radioactive material authorized for medical use in the license; and

7-004.03 Nothing in 180 NAC 7-004 relieves the licensee from complying with the requirements in 180 NAC 7.

7-005 U.S. FOOD AND DRUG ADMINISTRATION (FDA), FEDERAL AND STATE REQUIREMENTS: Nothing in this 180 NAC 7 relieves the licensee from complying with applicable FDA, Federal, and State requirements governing radioactive drugs or devices.

7-006 IMPLEMENTATION:

7-006.01 A licensee must implement the provisions in 180 NAC 7 on the effective date of these regulations, with the exception of requirements listed in 180 NAC 7-006.02.

7-006.02 When a requirement of 180 NAC 7 differs from the requirement in an existing license condition, the requirement in 180 NAC 7 will govern.

7-006.03 Any existing license condition that is not affected by a requirement in 180 NAC 7 remains in effect until there is a license amendment or license renewal.

7-006.04 If a license condition exempted a licensee from a provision of 180 NAC 7, it will continue to exempt a licensee from the corresponding provision in 180 NAC 7.

7-006.05 If a license condition cites provisions in 180 NAC 7 that has been deleted , then the license condition remains in effect until there is a license amendment or renewal that modifies or removes the license condition.

7-006.06 Licensees must continue to comply with any license condition that requires it to implement procedures required by 180 NAC 7-070, 7-076, 7-077 and 7-078 until there is a license amendment or renewal that modifies the license condition.

GENERAL REGULATORY REQUIREMENTS

7-007 LICENSE REQUIRED

7-007.01 A person may only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, or as allowed by 180 NAC 7-007.02 or 7-007.03.

7-007.02 An individual may receive, possess, use or transfer radioactive material in accordance with 180 NAC 7 under the supervision of an authorized user as provided in 180 NAC 7-018, unless prohibited by license condition.

7-007.03 An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in 180 NAC 7 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 180 NAC 7-018, unless prohibited by license condition.

7-008 APPLICATION FOR LICENSE, AMENDMENT, OR RENEWAL

7-008.01 An application must be signed by the applicant's or licensee's management.

7-008.02 An application for a license for medical use of radioactive material as described in 180 NAC 7-041, 7-044, 7-048, 7-055, 7-065, 7-067 and 7-085 must be made by filing an original of Form NRH-7 and 7A (Medical), "Application for Radioactive Material License - Medical". For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides.

7-008.03 A request for a license amendment or renewal may be submitted as an original in letter format. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide.

7-008.04 In addition to the requirements of 180 NAC 7-008.02 and 7-008.03, an application for a license or amendment for medical use of radioactive material as described in 180 NAC 7-085 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 180 NAC 7-001 through 7-040, as well as any specific information on:

1. Radiation safety precautions and instructions;
2. Training and experience of proposed users;
3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

7-008.05 An applicant or licensee must also provide any other information requested by the Department that has been determined to be reasonable and necessary for the review of the application.

7-008.06 An applicant that satisfies the requirements specified in 180 NAC 3-013.02 may apply for a Type A specific license of broad scope.

7-009 MOBILE MEDICAL SERVICE ADMINISTRATIVE REQUIREMENTS

7-009.01 The mobile medical service must be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service must be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

7-009.02 Mobile medical service licensees must obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter must clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letters must document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

7-009.03 A mobile medical service must not have radioactive material delivered directly 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.

7-009.04 A mobile medical service must inform the authorized user identified in 180 NAC 7-018.03 at each client's address of use at a time prior to the radioactive material being administered.

7-009.05 A licensee providing mobile medical services must retain the letter required in 180 NAC 7-009.02 in accordance with 180 NAC 7-097.

7-009.06 A mobile medical service licensee must, at a minimum, maintain the following documents on each mobile unit:

1. The current operating and emergency procedures;
2. A copy of the license;
3. Copies of the letter required by 180 NAC 7-009.02;
4. Current calibration records for each survey instrument, diagnostic equipment, and dose calibration systems in use;
5. Quality control tests and records of quality control required by 180 NAC 7-028; and
6. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

7-009.07 A mobile medical service licensee must maintain all records required by 180 NAC 4 and 7 at a location within the Department's jurisdiction that is:

1. A single address of use:

    a. Identified as the records retention location; and
    b. Staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection; or

2. On the mobile unit:

    a. Identified in the license; and
    b. Whose current client's address schedule and location is reported to the Department.

7-010 LICENSE AMENDMENTS: A licensee must apply for and receive a license amendment before:

7-010.01 Receiving, preparing or using radioactive material for a type of use that is permitted under 180 NAC 7-007, but that is not authorized on the licensee's current license issued under 180 NAC 7;

7-010.02 Permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

1. An authorized user, who meets the requirements in 180 NAC 7-027 and 7-043.01, 7-047.01, 7-051.01, 7-052.01, 7-053.01, 7-063.01, 7-066.01,and 7-084.01;
2. An authorized nuclear pharmacist, who meets the requirements in 180 NAC 7-024 and 7-027;
3. An authorized medical physicist, an individual who meets the requirements in 180 NAC 7-027 and 7-023.01 and 7-023.04; ;
4. Identified as an authorized user, authorized nuclear pharmacist or authorized medical physicist on a U.S. Nuclear Regulatory Commission or Agreement State or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively;
5. Identified as an authorized user on a permit that authorized nuclear pharmacist, or authorized medical physicist on a permit by a Nuclear Regulatory Commission or Agreement State specific license of broad scope that authorize the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

7-010.03 Changing a Radiation Safety Officer, except as provided in 180 NAC 7-015.05;

7-010.04 Receiving~~es~~ radioactive material in excess of the amount or in a different physical or chemical form, than is authorized on the license;

7-010.05 Adding to or changing the areas of use identified in the application or on the license;

7-010.06 Changing the address(s) of use identified in the application or on the license;

7-010.07 Changing statements, representations, and procedures which are incorporated into the license; and

7-010.08 Releasing licensed facilities for unrestricted use.

7-011 NOTIFICATIONS

7-011.01 A licensee must provide to the Department a copy of the board certification and the written attestation(s), signed by a preceptor, the U.S. Nuclear Regulatory Commission or Agreement State license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by a U.S. Nuclear Regulatory Commission or Agreement State licensee of a broad scope, or the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator produced radioactive materials, discrete sources of radium-226, 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 before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission and 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, pursuant to 180 NAC 7-010.02. For individuals permitted to work under 180 NAC 7-010.02, items within the same 30 day time frame, the licensee must also provide as appropriate, verification of completion of:

1. Any additional case experience required in 180 NAC 7-051.02, item 1.b.(6) for an authorized user under 180 NAC 7-048;
2. Any additional training required in 180 NAC 7-084.04 for an authorized user under 180 NAC 7-067; and
3. Any additional training required in 180 NAC 7-023.04 for an authorized medical physicist.

7-011.02 A licensee must notify the Department by letter no later than 30 days after:

1. 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; or
2. The licensee's mailing address changes; or
3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 180 NAC 3-017.02.

7-011.03 The licensee must mail documents required in 180 NAC 7-010 to the appropriate address identified in 180 NAC 1-002.

7-012 EXEMPTIONS REGARDING TYPE A SPECIFIC LICENSE OF BROAD SCOPE: A licensee possessing a Type A specific license of broad scope for medical use, issued under 180 NAC 03-013 is exempt from:

7-012.01 The provisions of 180 NAC 7-008.04 regarding the need to file an amendment to the license for medical use of radioactive material as described in 180 NAC 7-085.

7-012.02 The provisions of 180 NAC 7-010.02 regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;

7-012.03 The provisions of 180 NAC 7-010.05 regarding additions to or changes in the areas of use at the addresses specified in the license;

7-012.04 The provisions of 180 NAC 7-011.01 regarding notification to the Department for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists;

7-012.05 The provisions of 180 NAC 7-021.01 regarding supplier for sealed sources.

7-013 LICENSE ISSUANCE

7-013.01 The Department will issue a license for the medical use of radioactive material if:

1. The applicant has filed NRH-5A (Medical), “Application for Radioactive Material License – Medical” in accordance with instructions in 180 NAC 7-008.
2. The applicant has paid any applicable fee as provided in 180 NAC 18;
3. The applicant meets the requirements of 180 NAC 3; and
4. The Department finds the applicant equipped and committed to observe the safety standards established by the Department in 180 NAC for the protection of public health and safety.

7-013.02 The Department will issue a license for mobile medical service if the applicant:

1. Meets the requirements in 180 NAC 7-013.01; and
2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with 180 NAC 7-037.

7-014 SPECIFIC EXEMPTIONS: The Department may, upon application or upon its own initiative, grant such exemptions from the requirements of 180 NAC 7 as it determines are authorized by law and will not results in undue hazard to public health and safety or property.

GENERAL ADMINISTRATIVE REQUIREMENTS

7-015 RADIATION PROTECTION PROGRAM

7-015.01 The program must include notice to workers of the program's existence and workers responsibility to help keep dose equivalents ALARA, a review of the summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety measures, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make every reasonable effort to maintain individual and collective occupational doses ALARA.

7-015.02 The licensee must retain a current written description of the ALARA program for the duration of the license. The written description must include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;
2. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program; and
3. Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

7-015.03 In addition to the radiation protection program requirements of 180 NAC 4-004, a licensee's management will approve in writing: Requests for a license application, renewal, or amendment before submittal to the Department;

1. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and
2. Radiation protection program changes that do not require a license amendment and are permitted under 180 NAC 7-016;

7-015.04 A licensee's management must appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

7-015.05 For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer (RSO) to function as a temporary Radiation Safety Officer and perform the functions of a Radiation Safety Officer, as provided in 180 NAC 7-015.07, provided the licensee takes the actions required in 180 NAC 7-015.02, 7-015.06, 7-015.07 and 7-015.010. A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

7-015.06 A licensee must establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

7-015.07 A licensee must provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources and management prerogative to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and,
4. Verify implementation of corrective actions.

7-015.08 Licensees that are authorized for ~~one~~two or more different types of use under 180 NAC 7-048, 7-055, 7-067 and 7-085, or one or more types of units under 180 NAC 7-067, will establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members the licensee deems appropriate.

7-015.09 A licensee's Radiation Safety committee will meet as necessary, but at a minimum will meet at intervals not the exceed six months. The licensee will maintain minutes of each meeting in accordance with 180 NAC 7-086.

7-015.10 A licensee must retain a record of actions taken under 180 NAC 7-015.01, 7-015.02 and 7-015.05 in accordance with 180 NAC 7-086.

7-016 RADIATION PROTECTION PROGRAM CHANGES

7-016.01 A licensee may revise its radiation protection program without Department approval if:

1. The revision does not require a license amendment under 180 NAC 7-010;
2. The revision is in compliance with the regulations and the license;
3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
4. The affected individuals are instructed on the revised program before the changes are implemented.

7-016.02 A licensee must retain a record of each change in accordance with 180 NAC 7-087.

7-017 DUTIES OF AUTHORIZED USER AND AUTHORIZED MEDICAL PHYSICIST

7-017.01 Only authorized users for the type of radioactive material used can:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and
2. Direct, as specified in 180 NAC 7-018 and 7-019, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;
3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with 180 NAC 7-007.02, 7-007.03 and 7-018;
4. Perform the final interpretation of the results of tests, studies, or treatments.

7-017.02 Only authorized medical physicists can perform, as applicable:

1. Full calibration measurement as described in 180 NAC 7-073, 7-074, and 7-075; and
2. Radiation surveys as described in 180 NAC 7-080.

7-018 SUPERVISION

7-018.01 A licensee permitting the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 180 NAC 7-007.02, must:

1. In addition to the requirements of 180 NAC 10-003, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of 180 NAC 7, and the license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 180 NAC 7, and license conditions with respect to the medical use of radioactive material.
3. Require that only those individuals specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.
4. Require the authorized user to audit the performance of each supervised individual initially and at least annually. The audit must include verification that the supervised individual is meeting the requirements of 180 NAC 7-018.01, item 2 and physical observation of the individual performing the duties the authorized user has delegated to them.

7-018.02 A licensee permitting 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 180 NAC 7-007.03, must:

1. Train and instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of 180 NAC 7, and license conditions.

7-018.03 Unless physical presence as described in other sections of 180 NAC 7 is required, a licensee who permits supervised activities under 180 NAC 7-018.01 and 7-018.02 must require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and

7-018.04 A licensee that permits supervised activities under 180 NAC 7-018.01 and 7-018.02 is responsible for the acts and omissions of the supervised individual.

7-019 WRITTEN DIRECTIVES

7-019.01 A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

1. 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, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

7-019.02 The written directive must contain the patient or human research subject's name and the following information:

1. For any administration of dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and the route of administration;
2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
4. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
5. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

    a. Prior to implantation: treatment site, the radionuclide, and dose; and

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

7-019.03 A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

1. 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 will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

7-019.04 The licensee must retain a copy of the written directive in accordance with 180 NAC 7-088.

7-020 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

7-020.01 For any administration requiring a written directive, the licensee will develop, implement, and maintain written procedures to provide high confidence that:

1. The patient’s or human research subject’s identity is verified before each administration; and
2. Each administration is in accordance with the written directive.

7-020.02 The procedures required by 180 NAC 7-020.01 must, at a minimum, address the following items that are applicable to the licensee’s use of radioactive material:

1. Verifying the identity of the patient or human research subject:
2. Verifying that the specific details of the administration is in accordance with the treatment plan, if applicable, and the written directive.
3. Checking both manual and computer-generated dose calculations; and
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 180 NAC 7-067 or 7-085.

7-021 SUPPLIERS FOR SEALED SOURCES OR DEVICES FOR MEDICAL USE: For medical use, a licensee may only use:

7-021.01 Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 180 NAC 3 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, or another Agreement State;

7-021.02 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 180 NAC 3, or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

7-022 TRAINING FOR RADIATION SAFETY OFFICER: Except as provided in 180 NAC 7-026, the licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 180 NAC 7-015 to be:

7-022.01 An individual who is certified by a specialty board whose certification process has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission and who meets the requirements in 180 NAC 7-022.04 and 7-022.05. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.)

1. To have its certification process recognized, a specialty board will require all candidates for certification to:

   a. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
   b. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
   c. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. Require all candidates for certification to:

   a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
   b. Have two years of full-time practical training and/or supervised experience in medical physics:

      (1) Under the supervision of a medical physicist who is certified in medical physicist by a specialty board recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission; or
      (2) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements or for authorized users in 180 NAC 7-026, 7-047 or 7-

051.

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

7-022.02 An individual who:

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

a. 200 hours of classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology; and
(5) Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Department, U.S. Nuclear Regulatory Commission or Agreement State license or permit issued by the a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

(1) Shipping, receiving, and performing related radiation surveys;
(2) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
(3) Securing and controlling radioactive material;
(4) Using administrative controls to avoid mistakes in the administration of radioactive material;
(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
(6) Using emergency procedures to control radioactive material; and
(7) Disposing of radioactive material, or

7-022.03 An individual who is a:

1. Medical physicist who has been certified by a specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State in 180 NAC 7-023.01 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirement in 180 NAC 7-022.04 and 7-022.05; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and ~~who meets the requirements in 180 NAC 7-022.04 and 7-022.05.~~

7-022.04 An individual who has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 180 NAC 7-022.05 and in 180 NAC 7-022.01, item 1.a. and b. or 180 NAC 7-022.01, item 2.a. and b, or 180 NAC 7-022.02 item 1 or 180 NAC 7-022.03 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

7-022.05 An individual who has training in the radiation safety, regulatory issues and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

7-023 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST: Except as provided in 180 NAC 7-026 the licensee must require the authorized medical physicist to be:

7-023.01 An individual who is certified by a specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of 180 NAC 7-023.03 and 7-023.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
2. Have two years of full-time practical training and/or supervision experience in medical physics:

   a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission, or
   b. In a clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 180 NAC

7-026, 7-063 or 7-084; and

3. Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

7-023.02 An individual who:

1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

   a. Performing sealed source leak tests and inventories;
   b. Performing decay corrections;
   c. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
   d. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Meets the requirements of 180 NAC 7-023.03. and 7-023.04.

7-023.03 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-023.04 and 180 NAC 7-023.01, item 1 and 2, or 180 NAC 7-023.02, item 1 and 180 NAC 7-023.04, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 180 NAC 7-023, 7-026 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

7-023.04 Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by

an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

7-024 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST: The licensee will require the authorized nuclear pharmacist to be a pharmacist who:

7-024.01 Is certified by a specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-024.03. (The names of the board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) will be posted on the NRC's web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
2. Hold a current, active license to practice pharmacy;
3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience;
4. Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

7-024.02 Completed all of the following requirements:

1. 700 hours in a structured educational program consisting of both:

   a. 200 hours of classroom and laboratory training in the following areas:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity;
      (4) Chemistry of radioactive material for medical use; and
      (5) Radiation biology; and

   b. Supervised practical experience in nuclear pharmacy involving:

      (1) Shipping, receiving, and performing related radiation surveys;
      (2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(3) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
(4) Using administrative controls to avoid medical events in the administration of radioactive material; and
(5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Meets the requirement of 180 NAC 7-024.03.

7-024.03 Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements of 180 NAC 7-024.01, item 1, 2, and 3 or 7-024.02 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

7-025 TRAINING AND TECHNICAL REQUIREMENT FOR NUCLEAR MEDICINE TECHNOLOGISTS AND RADIATION THERAPISTS

7-025.01 The licensee will require a individual performing nuclear medicine technology under the supervision of an authorized user to be an individual who:

1. Is certified in;

   a. Nuclear Medicine by the Nuclear Medicine Technology Certification Board (NMTCB);
   b. Nuclear Medicine by the American Registry of Radiologic Technologists (ARRT) with competency in Nuclear Medicine; or,

2. Be board eligible to take the NMTCB or ARRT(N) examinations; or,
3. Has successfully completed a training program in nuclear medicine which has resulted in certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,
4. Has training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:

   a. 200 hours of classroom and laboratory training in the following areas:

      (1) Radiation Physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity;
      (4) Chemistry of radioactive material for medical use; and
      (5) Radiation biology;
      (6) Imaging Technology; and

   b. Work experience, under the supervision of an authorized user involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(3) Calculating, measuring, and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

c. Supervised clinical experience under the supervision of an authorized user that includes:

(1) Reviewing the case histories of individuals to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
(2) Identifying radiopharmaceuticals for clinical procedures and calculating and measuring the dosages;
(3) Administering dosages to individuals and using syringe radiation shields; and
(4) Acquiring and manipulating diagnostic data.

d. Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of 180 NAC 7-025.01, item 4.a. and b. and has achieved a level of radiation safety competency sufficient to independently function as a nuclear medicine technologist.

7-025.02 The licensee must require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or
2. Be board eligible to take the ARRT(T) examination; or,
3. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology,[1] or,
4. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

[1] "Essentials and guidelines of an Accredited Education Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, January 1, 2002.

a. 200 hours of classroom and laboratory training in the following areas:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and
(4) Radiation biology; and

b. Work experience, under the supervision of an authorized user involving:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Assisting the authorized user in simulating the patient for treatment;
(3) Preparing the patient for treatment;
(4) Implementing treatment plans as prescribed by the authorized user;
(5) Providing written documentation of treatment setup and patient treatments;
(6) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
(7) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
(8) Delivering doses to patients or human research subjects under the supervision of the authorized user;
(9) Maintaining running inventories of radioactive material on hand;
(10) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,
(11) Properly implementing emergency procedures; and

c. Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of 180 NAC 7-025.02 item 4.a. and 4.b. and has achieved a level of radiation safety competency sufficient to independently function as a radiation therapist.

7-025.03 The licensee must maintain records of the above training as specified in 180 NAC 7-100.

7-026 PROVISIONS FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST AND AUTHORIZED NUCLEAR PHARMACIST

7-026.01 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist or a authorized medial physicist, or a authorized nuclear pharmacist on a U.S. Nuclear Regulatory Commission, an Agreement State, or a Department license or on a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State or a Department broad scope licensee or master material license permit

or by a master material licensee permittee of broad scope that authorizes medical use or practice of nuclear pharmacy, before July 11, 2009 ~~the effective date of these regulations~~ need not comply with the training requirements of 180 NAC 7-022 through 7-024.

7-026.02 Physicians, dentists, or podiatrists identified as authorized users for the medical, use of radioactive material on a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or the Department, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission, an Agreement State or the Department broad scope licensee, or on a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee before July 11, 2009 ~~the effective date of these regulations~~, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements 180 NAC 7-041 through 7-084 .

7-26.03 Individuals who need not comply with training requirements as described in 180 NAC 7-026 may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

7-027 RECENTNESS OF TRAINING: The training and experience specified in 180 NAC 7 must have been obtained within seven years preceding the date of license application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

7-028 QUALITY CONTROL OF DIAGNOSTIC EQUIPMENT: Each licensee must establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies must be those recommended by equipment manufacturers or procedures, which have been approved by the Department. The licensee must conduct quality control procedures in accordance with written procedures.

7-029 POSSESSION, USE, AND CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTIVITY OF UNSEALED RADIOACTIVE MATERIAL

7-029.01 For direct measurements performed in accordance with 180 NAC 7-031, a licensee must possess and use instrumentation to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject.

7-029.02 A licensee must test the instrumentation required in 180 NAC 7-029.01 in accordance with nationally recognized standards or the manufacturer's instructions.

7-029.03 The tests required in 180 NAC 7-029.02 must at minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

7-029.04 A licensee will must a record of each instrument test required by 180 NAC 7-029 in accordance with 180 NAC 7-091.

7-030 CALIBRATION OF SURVEY INSTRUMENTS

7-030.01 A licensee must ensure that the survey instruments used to show compliance with 180 NAC 7 and 180 NAC 4 have been calibrated before first use, annually and following any repair that affects the calibration.

7-030.02 To satisfy the requirements of 180 NAC 7-030.01, the licensee must:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with a radiation source;
2. Have each radiation survey instrument calibrated:

    a. At energies appropriate for use and at annual intervals or after servicing instrument, except for battery changes;
    b. For linear scale instruments at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range and each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 mSv (2 and 1,000 mrem) per hour; and
    c. For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

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

7-030.03 The licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%.

7-030.04 A licensee must check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

7-030.05 A licensee must maintain a record of each survey instrument calibration in accordance with 180 NAC 7-092.

7-031 DETERMINATION OF DOSAGES OF RADIOACTIVE MATERIAL FOR MEDICAL USE

7-031.01 A licensee must determine and record the activity of each dosage prior to medical use.

7-031.02 For unit dosages not requiring a written directive, this determination must be made by:

1. Direct measurement of radioactivity; or

2. A decay calculation, based on the measurements made by:
   a. A manufacturer or preparer licensed pursuant to 180 NAC 3 or equivalent provision of the U.S. Nuclear Regulatory Commission or Agreement State or
   b. A Department, U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigation New Drug (IND) protocol accepted by FDA; or
   c. A PET radioactive drug producer licensed in 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

7-031.03 For unit dosages requiring a written directive this determination must be made by direct measurement of radioactivity in accordance with 180 NAC 7-029.

7-031.04 For other than unit dosages not requiring a written directive, this determination must be made bydirect measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 180 NAC 3 or equivalent provision of the U.S. Nuclear Regulatory Commission or Agreement State or a PET radioactive drug producer licensed in 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

7-031.05 For other than unit dosages requiring a written directive this must be made by direct measurement of radioactivity in accordance with 180 NAC 7-029.

7-031.06 A licensee may not use a dosage if the dosage differs from the prescribed dosage by more than 20%.

7-031.07 A licensee must retain a record of the dosage determination required by 180 NAC 7 in accordance with 180 NAC 7-093.

7-032 AUTHORIZATION FOR CALIBRATION, TRANSMISSION AND REFERENCE SOURCES: Any person authorized by 180 NAC 7-007 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

7-032.01 Sealed sources manufactured and distributed by persons specifically licensed pursuant to 180 NAC 3 or equivalent provisions of the U.S. Nuclear Regulatory Commission, or Agreement State and that do not exceed 1.11 GBq (30 mCi) each;

7-032.02 Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 MBq (15 mCi);

7-032.03 Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

1. 7.4 MBq (200 μCi); or
2. 1000 times the quantities in Appendix B of 180 NAC 3 and

7-032.04 Technetium-99m in amounts as needed.

7-033 REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES

7-033.01 A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer, or equivalent instructions approved by the Department.

7-033.02 A licensee in possession of a sealed source must:

1. Test the source for leakage in accordance with 180 NAC 1-011; and.
2. Test the source for leakage at intervals not to exceed six months or at intervals approved by the Department, another Agreement State, or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

7-033.03 If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee must:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of 180 NAC 1-011.06 and 180 NAC 4; and
2. File a report within five days of the leak test in accordance with 180 NAC 7-118.

7-033.04 A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotatic radiosurgery sources, must conduct a semi-annual physical inventory of all such sources. The licensee must retain each inventory record in accordance with 180 NAC 7-094

7-034 LABELS: Each syringe and vial that contains a 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.

7-035 VIAL SHIELDS AND SYRINGE SHIELD

7-035.01 A licensee must require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

7-035.02 A licensee must keep syringes that contain radioactive material to be administered in a radiation shield.

7-035.03 A licensee must require each individual who prepares or administers radioactive drugs to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

7-036 SURVEYS FOR AMBIENT RADIATION DOSE RATE AND CONTAMINATION

7-036.01 ~~Except as provided in 180 NAC 7-036.02 a~~ A licensee must survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs ~~containing radioactive material requiring a written directive were~~ are routinely prepared for use or administered.

7-036.02 A licensee must survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

7-036.03 A licensee must conduct the surveys required by 180 NAC 7-036.01 and 7-036.02 so as to be able to measure dose rates as low as 1 μSv (0.1 mrem) per hour.

7-036.04 A licensee must establish dose rate action levels for the surveys required by 180 NAC 7-036.01 and 7-036.02 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

7-036.05 A licensee must survey for:

1. Removable contamination once each day all areas where generators and bulk radioactive drugs are prepared for use or administered.
2. Removable contamination once each week where unsealed radioactive materials are prepared for use or administered and where unsealed radioactive materials are stored.

7-036.06 A licensee must conduct the surveys required by 180 NAC 7-036.05 so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm).

7-036.07 A licensee must establish removable contamination action levels for the surveys required by 180 NAC 7-036.05 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

7-036.08 A licensee must retain a record of each survey in accordance with 180 NAC 7-095.

7-037 RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS

7-037.01 A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive drugs 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 5 mSv (0.5 rem).[2]

7-037.02 For patients administered radioactive material for which a written directive is required, a licensee must provide the released individual, or individual's parent or guardian with oral and 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 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

1. Guidance on the interruption or discontinuation of breast-feeding and
2. Information on the potential consequences, if any, of failure to follow the guidance.

7-037.03 Release of the patient must be approved by an individual listed as an authorized user on the Department license or an approved individual who is operating directly under the supervision of the authorized user and that authorized user is approved for the type of radioactive material use for which the patient being released has received.

7-037.04 The licensee must maintain a record of the basis for authorizing the release of an individual in accordance with 180 NAC 7-096.

7-037.05 The licensee must maintain a record of instructions provided to a breast-feeding female in accordance with 180 NAC 7-096.

7-037.06 The licensee must notify the Department in accordance with 180 NAC 7-119:

1. When they are aware that a patient containing radioactive material and who has been released in accordance with 180 NAC 7-037 dies; and,
2. If it is possible that any individual could receive exposures in excess of 5 mSV (500 mrem) as a results of the deceased's body.

7-038 MOBILE MEDICINE SERVICE TECHNICAL REQUIREMENTS: A licensee providing mobile nuclear medicine service must:

7-038.01 Transport to each address of use only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

7-038.02 Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

[2]U.S. Nuclear Regulatory Commission's - NUREG-1556, Vol.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 5 mSv (0.5 rem).

7-038.03 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

7-038.04 Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each address of use or on each day of use, whichever is more frequent. At a minimum, the check for proper function must include a constancy check;

7-038.05 Check survey instruments for consistent response with a dedicated check source before use at each client's address;

7-038.06 Prior to leaving a client's address of use, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with the requirements in 180 NAC 4.

7-038.07 Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and,

7-038.08 Retain a record of each survey required by 180 NAC 7-038.05 in accordance with 180 NAC 7-097.

7-039 STORAGE AND CONTROL OF VOLATILES AND GASES

7-039.01 A licensee must store volatile radioactive material and radioactive gases in a radiation shield and container.

7-039.02 A licensee must store and use a multi-dose container in a properly functioning fume hood.

7-039.03 A licensee who administers radioactive aerosols or gases must do so with a system that will keep airborne concentrations within the limits prescribed in 180 NAC 4.

7-039.04 The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

7-039.05 A licensee must check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements must be maintained for three years.

7-039.06 A licensee must only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

7-039.07 Before receiving, using, or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix 4-B of 180 NAC 4. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

7-039.08 A licensee must post the time calculated in 180 NAC 7-039.07 at the area of use and requires that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

7-039.09 A copy of the calculations required in 180 NAC 7-039.07 must be recorded and retained for the duration of the license.

7-040 DECAY-IN-STORAGE: See 180 NAC 4-039.03 for decay-in-storage requirements.

UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED

7-041 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for diagnostic use involving measurements of uptake, dilution, or excretion that is:

7-041.01 Obtained from:

1. A manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent regulations of the U.S. Nuclear Regulatory Commission or Agreement State; or
2. A PET radioactive drug producer licensed pursuant to 180 NAC 3-010.11 or equivalent regulations of the U.S. Nuclear Regulatory Commission or Agreement State; or

7-041.02 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 180 NAC 7-047 or 7-051 and 7-047.03, item 1.b.(7); or
3. An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 180 NAC 7-041.02, item 1 or the physician who is authorized user in 180 NAC 7-041.02, item 2; or

7-041.03 Obtained from and prepared by an U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7-041.04 Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7-042 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material for uptake, dilution, and excretion studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μSv (0.1 mrems) per hour to 1000 μSv (100 mrems) per hour. The instrument must be operable and calibrated in accordance with 180 NAC 7-030.

7-043 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in 180 NAC 7-041 to be a physician who:

7-043.01 Is certified by a medical specialty board whose certification process has been recognized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 180 NAC 7-043.04. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 180 NAC 7-043.03, items 1.and 2; and
2. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

7-043.02 Is an authorized user under 180 NAC 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or

7-043.03 Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in the following areas:

    a. Radiation physics and instrumentation;
    b. Radiation protection;
    c. Mathematics pertaining to the use and measurement of radioactivity;
    d. Chemistry of radioactive material for medical use; and
    e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the

requirements in 180 NAC 7-026, 7-043, 7-047 or 7-051 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
c. Calculating, measuring, and safely preparing patient or human research subject dosages;
d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
f. Administering dosages of radioactive drugs to patients or human research subjects; and

3. Meet the requirements of 180 NAC 7-043.04.

7-043.04 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-043, 7-047, or 7-051, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirement in 180 NAC 7-043.01, item 1 or 7-043.03, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 180 NAC 7-041.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE NOT REQUIRED

7-044 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 180 NAC 7-019 that is:

7-044.01 Obtained from:
1. A manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State ; or
2. A PET radioactive drug producer licensed pursuant to 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State; or

7-044.02 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 180 NAC 7-047, or 7-051 and 7-047.03, item 1.b.(7), or
3. An individual under the supervision, as specified in 180 NAC 7-018; of, the

authorized nuclear pharmacist in paragraph 180 NAC 7-044.02, item 1 or the physician who is an authorized user in paragraph 180 NAC 7-044.02, item 2;

7-044.03 Obtained from and prepared by an U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7-044.04 Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

7-045 RADIONUCLIDE CONTAMINANTS

7-045.01 A licensee must not administer to humans a radioactive drug containing:

1. More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m).
2. More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-82 per mCi of rubidium-82 chloride injection).
3. More than 0.02 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-85 per mCi of rubidium-82 chloride injection).

7-045.02 To demonstrate compliance with 180 NAC 7-045, the licensee preparing radioactive drugs from radionuclide generators must:

1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

7-045.03 A licensee that uses strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 180 NAC 7-045.01.

7-045.04 A licensee who must measure radionuclide concentration must retain a record of each measurement in accordance with 180 NAC 7-099.

7-045.05 A licensee must report immediately to the Department each occurrence of a concentration exceeding the limits specified in 180 NAC 7-045.01.

7-046 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for imaging and localization studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour. If generators (Mo99/Tc99m or Sr82/Rb82) are utilized, a portable

radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-047 TRAINING FOR IMAGING AND LOCALIZATION STUDIES: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized in 180 NAC 7-044 to be a physician who:

7-047.01 Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets to requirement in 180 NAC 7-047.04. (The names of board certification which have been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 180 NAC 7-047.03, item 1.a. through item 1.b.(7) ; and
2. Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

7-047.02 Is an authorized user in 180 NAC 7-051 and meets the requirements in 180 NAC 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

7-047.03 The physician:

1. Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include at a minimum:

    a. Classroom and laboratory training in the following areas:

        (1) Radiation physics and instrumentation;
        (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
        (3) Mathematics pertaining to the use and measurement of radioactivity;
        (4) Chemistry of radioactive material for medical use;
        (5) Radiation biology; and

b. Work experience, under the supervision of an authorized user, who meets the requirements in 180 NAC 7-026, 7-047, or 7-051 and 7-047.03, item 1.b.(7)~~, and 180 NAC 7-051~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving;

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(3) Calculating, measuring, and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
(6) Administering dosages of radioactive drugs to patients or human research subjects; and
(7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Meets the requirement of 180 NAC 7-047.04.

7-047.04 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-047, or 7-051 and 7-047.03, item 1.b.(7) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-047.01, item 1 or 180 NAC 7-047.03, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-041 and 7-044 .

UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE REQUIRED

7-048 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

7-048.01 Obtained from:
1. A manufacturer or preparer licensed in 180 NAC 3-014.10; or equivalent U.S. Nuclear Regulatory Commission or Agreement State; or
2. A PET radioactive drug producer licensed pursuant to 180 NAC 3-010.11 or equivalent U.S. Nuclear Regulatory Commission or Agreement State; or

7-048.02 Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-047 or 7-051;
2. An individual under the supervision of either as specified in 180 NAC 7-018; or
3. An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 7-048,02, item 1 or the physician who is authorized in 7-048.02, item 2; or

7-048.03 Obtained from and prepared by the Department, U.S. Nuclear Regulatory Commission or Agreement State licensee in accordance with a Radioactive Drug Research Committee's approval protocol or an Investigational New Drug (IND) protocol accepted by FDA for use in research; or

7-048.04 Prepared by the licensee for use in research in accordance with an approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7-049 SAFETY INSTRUCTION AND SAFETY PRECAUTIONS

7-049.01 In addition to the requirements of 180 NAC 10-003,

1. A licensee must provide radiation safety instruction to all personnel caring for patients or human research subjects that have received therapy with radioactive drug, and cannot be released in accordance with 180 NAC 7-037. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

    a. Patient or human research subject control;
    b. Visitor control to include the following:

        (1) Routine visitation to hospitalized individuals in accordance with 180 NAC 4-013.01, item 1; and
        (2) Visitation authorized in accordance with 180 NAC 4-013.03.

    c, Contamination control;
    d. Waste control; and
    e. Notification of the Radiation Safety Officer or his/her designee and the authorized user if the patient or the human research subject has a medical emergency or dies.

2. A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-101.

7-049.02 Safety Precautions

1. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-037, a licensee must:

a. Quarter the patient or the human research subject either in:

(1) A private room with a private sanitary facility; or
(2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who also cannot be released under 180 NAC 7-037;

b. Visibly post the patient's or the human research subject's door with a "Caution: Radioactive Materials" sign and 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; and

c. Either:

(1) 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
(2) Handle such material and items as radioactive waste.

2. The Radiation Safety Officer, or his/her designee, and the authorized user must be notified immediately if the hospitalization patient dies or has a medical emergency. The licensee must also notify the Department in accordance with 180 NAC 7-119 if it is possible that any individual could receive exposures in excess of 180 NAC 4-013 as a result of the deceased's body.

3. Measure the thyroid burden of each individual who helped prepare or administer a liquid dosage of iodine-131 or in all cases where the patient's vomits or the capsule is compromised. The measurement must be done within three days after administering the dosage, and retain for the period required by 180 NAC 4-052 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

7-050 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for which a written directive is required must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μSv (0.1 mrem) per hour to 1,000 μSv (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 μSv (1 mrem) per hour to 10 mSV (1000 mrems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-051 TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A

WRITTEN DIRECTIVE IS REQUIRED: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of unsealed radioactive material for the uses authorized under 180 NAC 7-048 to be a physician who:

7-051.01 Is certified by a medical specialty board whose certification process has been recognized by the Department an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) who meets the requirements in 180 NAC 7-051.02, item 1.b.(6) and 7-051.03. (Specialty Boards whose certification process has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) To be recognized, a specialty board must require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 180 NAC 7-051.02, item 1.a. through 7-051.02, item 1.b.(5). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

7-051.02 The physician:

1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

   a. Classroom and laboratory training in the following areas:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity;
      (4) Chemistry of radioactive material for medical use; and
      (5) Radiation biology; and

   b. Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, or equivalent U.S. Nuclear Regulatory or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must also have

experience in administering dosages in the same dosage category or categories (that is , 180 NAC 7-051.02, item 1., b.(6)) as the individual requesting authorized user status. The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
(3) Calculating, measuring, and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
(6) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(a) Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131, for which a written directive is required;
(b) Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131[3];
(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
(d) Parenteral administration of any other radionuclide, for which a written directive is required; and

2. Meets the requirements of 180 NAC 7-051.03.

7-051.03 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-051.01, item 1 and 7-051.02, item 1.b.(6) or 7-051.02, item 1 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirement in 180 NAC 7-051.02 must have experience in administering dosages in the same dosage category or categories (that is, 180 NAC 7-051.02, item 1.b.(6)) as the individual requesting authorized user status.

7-052 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 IN

[3]Experience with at least 3 cases in 180 NAC 7-051.02, item 1.b. (6) (b) also satisfies the requirement in 180 NAC 7-051.02, item 1.b.(6)(a).

QUANTITIES LESS THAN OR EQUAL TO 1.22 GIGABECQUERELS (33 MILLICURIES) FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 GBq (33 mCi), for which a directive is required, to be a physician who:

7-052.01 Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-052.03, item 1. and 2. and whose certification has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission who meets the requirements of 180 NAC 7-052.04. (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.) or

7-052.02 Is an authorized user under 180 NAC 7-051.01, 7-051.02 for uses listed in 180 NAC 7-051.02, item 1.b.(6)(a) or (b), 180 NAC 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

7-052.03 The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

    a. Radiation physics and instrumentation;
    b. Radiation protection;
    c. Mathematics pertaining to the use and measurement of radioactivity;
    d. Chemistry of radioactive material for medical use; and
    e. Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b). The work experience must involve:

    a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    b. Performing quality control procedures on instruments used to determine the activity of dosages and performing check for proper operation of survey meters;
    c. Calculating, measuring, and safely preparing patient or human research subject dosages;
    d. Using administrative controls to prevent a misadministration involving the use of radioactive material;
    e. Using procedures to contain spilled radioactive material safely and using

proper decontamination procedures; and

f. Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131; and

3. Meets the requirements of 180 NAC 7-052.04.

7-052.04 Has obtained written attestation that the individual has satisfactorily completed the requirements in180 NAC 7-052.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-052, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(a) or (b).

7-053 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE 1-131 IN QUANTITIES GREATER THAN 1.22 GIGABECQUERELS (33 MILLICURIES) FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the oral administration of sodium iodide 1-131 in quantities greater than 1.22 GBq (33 mCi), to be a physician who:

7-053.01 Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-053.03, item 1. and 2. and whose certification has been recognized the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC)and who meets the requirements in 180 NAC 7-053.04. (The name of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's Web page.) or

7-053.02 Is an authorized user under 180 NAC 7-051, for uses listed in 180 NAC 7-051.02, item 1.b.(6)(b), or equivalent Agreement State, or U.S. Nuclear Regulatory Commission requirements; or

7-053.03 The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

a. Radiation physics and instrumentation;
b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity;
d. Chemistry of radioactive material for medical use; and
e. Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-053, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(b). The work experience must involve:

   a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
   b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
   c. Calculating, measuring, and safely preparing patient or human research subject dosages;
   d. Using administrative controls to prevent a misadministration event involving the use of radioactive material;
   e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
   f. Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131; and

3. Meets the requirement of 180 NAC 7-053.04.

7-053.04 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-053.03, item 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 180 NAC 7-048. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051 or, 7-053, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051.02, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.(6)(b).

7-054 TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE: Except as provided in 180 NAC 7-026, the licensee must require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

7-054.01 Is an authorized user under 180 NAC 7-051 for uses listed in 7-051.02, item 1.b. (6)(c) or (d),or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

7-054.02 Is an authorized user under 180 NAC 7-063 or 7-084, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who meets the requirements in 180 NAC 7-054.04; or

7-054.03 Is certified by a medical specialty board whose certification process has been recognized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State under 180 NAC 7-063 or 7-084; and who meets the requirements in 180 NAC 7-054.04.

7-054.04 The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

    (1) Radiation physics and instrumentation;
    (2) Radiation protection;
    (3) Mathematics pertaining to the use and measurement of radioactivity;
    (4) Chemistry of radioactive material for medical use; and
    (5) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051 or 7-054, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d). The work experience must involve:

    a. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
    b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
    c. Calculating, measuring, and safely preparing patient or human research subject dosages;
    d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
    e Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
    f. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at

least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-054.02 or 7-054.03, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, or 7-054, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 180 NAC 7-051, must have experience in administering dosages as specified in 180 NAC 7-051.02, item 1.b.(6)(c) and/or (d).

MANUAL BRACHYTHERAPY

7-055 USE OF SOURCES FOR MANUAL BRACHYTHERAPY: A licensee must use only brachytherapy sources for therapeutic medical uses:

7-055.01 As approved in the Sealed Source and Device Registry; or

7-055.02 For research in accordance with an active Investigational Device Exemption (IDE) application that has been accepted by the FDA, provided the requirements of 180 NAC 7-021.01 are met.

7-056 SURVEYS AFTER SOURCE IMPLANT AND REMOVAL

7-056.01 Immediately after implanting sources in a patient or a human research subject, the licensee must make a survey to locate and account for all sources that have not been implanted.

7-056.02 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must 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.

7-056.03 A licensee must retain a record of the surveys in accordance with 180 NAC 7-102.

7-057 BRACHYTHERAPY SOURCES INVENTORY

7-057.01 A licensee must maintain accountability at all times for all brachytherapy sources in storage or use.

7-057.02 Promptly after removing sources from a patient or a human research subject, a licensee must return brachytherapy sources to a secure storage area.

7-057.03 A licensee must maintain a record of the brachytherapy source accountability in accordance with 180 NAC 7-103.

7-058 SAFETY INSTRUCTION: In addition to the requirements of 180 NAC 10-003,

7-058.01 The licensee must provide radiation safety instruction, initially and at least annually, to personnel caring for a patient or human research subjects that are undergoing implant therapy and can not be released under 180 NAC 7-037. The instruction must be commensurated with the duties of the personnel and will include the following:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;
4. Visitor control, including both:

    a. Routine visitation of hospitalized individual in accordance with 180 NAC 4-013.01 and
    b. Visitation authorized in accordance with 180 NAC 4-013.01; and

5. Notification of the Radiation Safety Officer or his/her designee, and authorized user if the patient or the human research subject dies or has a medical emergency. The licensee will also notify the Department in accordance with 180 NAC 7-119 if it is possible that any individual could receive exposures in excess of 5 mSv (500 mrem) as a result of the deceased's body.

7-058.02 A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-101.

7-059 SAFETY PRECAUTIONS FOR PATIENTS OR HUMAN RESEARCH SUBJECTS RECEIVING BRACHYTHERAPY

7-059.01 For each patient or human research subject that is receiving brachytherapy that cannot be released pursuant to 180 NAC 7-037 a licensee must:

1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and
2. Visibly post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign; and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

7-059.02 A licensee must have radiological emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

1. Dislodged from the patient; and
2. Lodged within the patient following removal of the source applicators.

7-059.03 The Radiation Safety Officer, or his/her designee, and authorized user must be notified immediately if the hospitalized patient or human research subject has a medical emergency or dies.

7-060 CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES

7-060.01 Prior to the first medical use of a brachytherapy source a licensee must have performed the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of 180 NAC 7-072.01;
2. Determine source positioning accuracy within applicators; and
3. Use published protocols currently accepted by nationally recognized bodies to meet the requirements of 180 NAC 7-060.01, item 1. and 2.

7-060.02 A 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 180 NAC 7-060.01.

7-060.03 A licensee must mathematically correct the outputs or activities determined in 180 NAC 7-060.01 for physical decay at intervals consistent with one percent physical decay.

7-060.04 An authorized medical physicist must perform or review the calculation measurements made pursuant to 180 NAC 7-060.01, 7-060.02, or 7-060.03.

7-060.05 Only an authorized medical physicist must 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 in accordance with 180 NAC 7-060.01, 7-060.02, or 7-060.03.

7-060.06 A licensee must retain a record of each calibration in accordance with 180 NAC 7-104.

7-060.07 A licensee must retain a record of decay calculations required by 180 NAC 7-060.5 in accordance with 180 NAC 7-105.

7-061 THERAPY-RELATED COMPUTER SYSTEMS: The licensee must 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:

7-061.01 The source-specific input parameters required by the dose calculation algorithm;

7-061.02 The accuracy of dose, dwell time, and treatment time calculations at

representative points;

7-061.03 The accuracy of isodose plots and graphic displays; and

7-061.04 The accuracy of the software used to determine sealed source positions from radiographic images.

7-062 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use manual brachytherapy sources must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μSv (0.1 mrem) per hour to 1,000 μSv (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 μSv (1 mrem) per hour to 10 mSv (1000 mrems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-063 TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of a manual brachytherapy source for the uses authorized under 180 NAC 7-055 to be a physician who:

7-063.01 Is certified by a medical specialty board whose certification has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC), and who meets to requirements of 180 NAC 7-063.03. (The names of board certifications which have been recognized an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's Web page.) To have its certification process recognized, a specialty board must require all candidates for certification to:

1. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
2. Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use manual brachytherapy; or

7-063.02 The physician:

1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

    a. 200 hours of classroom and laboratory training in the following areas:

        1. Radiation physics and instrumentation;
        2. Radiation protection;
        3. Mathematics pertaining to the use and measurement of

radioactivity; and

4. Radiation biology; and

b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a misadministration involving the use of radioactive material;
6. Using emergency procedures to control radioactive material; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 180 NAC 7-026, 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements, as a part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdocutoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 180 NAC 7-063.02, item 1.b.; and

3. Meet the requirements of 180 NAC 7-063.03.

7-063.03 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-063, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-063.01, item 1 or 7-063.02, item 1 and 2 and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 180 NAC 7-055.

7-064 TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90: Except as provided in 180 NAC 7-026, the licensee must require the authorized user of strontium-90 for ophthalmic uses authorized under 180 NAC 7-055 to be a physician who:

7-064.01 Is an authorized user under 180 NAC 7-063 or equivalent U.S. Nuclear Regulatory or Agreement State requirements; or

7-064.02 The physician:

1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

   a. Radiation physics and instrumentation;
   b. Radiation protection;
   c. Mathematics pertaining to the use and measurement of radioactivity; and
   d. Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

   a. Examination of each individual to be treated;
   b. Calculation of the dose to be administered;
   c. Administration of the dose; and
   d. Follow up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-063 or 7-064 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-064.01 and 7-064.02 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

SEALED SOURCES FOR DIAGNOSIS

7-065 USE OF SEALED SOURCES FOR DIAGNOSIS: A licensee must use only sealed sources for diagnostic medical uses:

7-065.01 Approved in the U.S. Nuclear Regulatory Commission's Sealed Source and Device Registry; and

7-065.02 Handled in accordance with the manufacturer's radiation safety instructions.

7-066 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS: Except as provided in 180 NAC 7-026, the licensee must require the authorized user of a diagnostic sealed source for use in a device authorized under 180 NAC 7-065 to be a physician, dentist or podiatrist who:

7-066.01 Is certified by a specialty board whose certification includes all of the requirements in 180 NAC 7-066.02 and 7-066.03 whose certification has been recognized by, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC). (The names of board certifications which have been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission will be posted on the NRC's Web page.); or

7-066.02 The physician, dentist, or podiatrist:

1. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

    a. Radiation physics and instrumentation;
    b. Radiation protection;
    c. Mathematics pertaining to the use and measurement of radioactivity; and
    d. Radiation biology; and

7-066.03 Has completed training in the use of the device for the uses requested.

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPHY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-067 USE OF A SEALED SOURCE IN A REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNIT: A licensee must use sealed sources in photon emitting remote afterloader units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

7-067.01 As approved in the U.S. Nuclear Regulatory Commission Sealed Source and Device Registry; or

7-067.02 For research in accordance with an active Investigational Device Exemption (IDE) application that has been accepted by the FDA provided the requirements of 180 NAC 7-021.01 are met.

7-068 SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS TREATED WITH A REMOTE AFTERLOADER UNIT

7-068.01 Before releasing a patient or a human research subject from licensee control, a licensee must make a survey of 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 shielded position.

7-068.02 A licensee must retain a record of surveys in accordance with 180 NAC 7-102.

7-069 INSTALLATION, MAINTENANCE, ADJUSTMENT, AND REPAIR

7-069.01 Only a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State may 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).

7-069.02 Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State may install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

7-069.03 For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or an authorized medical physicist may install, replace, relocate, or remove a sealed source(s) contained in the unit.

7-069.04 A licensee must retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 180 NAC 7-106.

7-070 SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPHY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-070.01 A licensee must:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
3. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

    a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
    b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
    c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

7-070.02 A copy of the procedures required by 180 NAC 7-070.01, item 4 must be physically located at the unit console.

7-070.03 A licensee must post instructions at the unit console to inform the operator of:

1. The location of the procedures required by 180 NAC 7-70.01, item 4; and
2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

7-070.04 A licensee must provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

1. The procedures identified in 180 NAC 7-070.01, item 4; and
2. The operating procedures for the unit.

7-070.05 A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

7-070.06 A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-070.04, in accordance with 180 NAC 7-101.

7-071 SAFETY PRECAUTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-071.01 A licensee must control access to the treatment room by a door at each entrance.

7-071.02 A licensee must equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
2. Cause the source(s) to be shielded promptly when an entrance door is opened; and
3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

7-071.03 A licensee must require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

7-071.04 Except for low-dose remote afterloader units, a licensee will 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.

7-071.05 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.

7-071.06 In addition to the requirements specified in 180 NAC 7-071.01 through 7-071.05, a licensee must:

1. For low dose-rate, medium dose-rate and pulsed dose-rate remote afterloader units, require:

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

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

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

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

4. Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency and immediately if the patient dies.

7-071.07 A licensee must have applicable radiological emergency response equipment available near each treatment room to respond to a source that inadvertently:

1. Remains in the unshielded position; or
2. Lodges within the patient following completion of the treatment.

7-072 DOSIMETRY EQUIPMENT

7-072.01 Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following conditions must be met.

1. The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or
2. The system must have been calibrated within the previous four years. Within 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee must 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.

7-072.02 The licensee must have available for use a dosimetry system 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 180 NAC 7-072.01. 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 180 NAC 7-072.01.

7-072.03 The licensee must retain a record of each calibration, intercomparison, and comparison in accordance with 180 NAC 7-107.

7-073 FULL CALIBRATION MEASUREMENTS ON TELETHERAPY UNITS

7-073.01 A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

7-073.02 To satisfy the requirement of 180 NAC 7-073.01, full calibration measurements must include determination of:

1. The output within +/-3% for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy, and linearity over the range of use;
5. “On-off" error; and
6. The accuracy of all distance measuring and localization devices in medical use.

7-073.03 A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required by 7-073.02, item 1. may then be made using a dosimetry system that indicates relative dose rates.

7-073.04 A licensee must make full calibration measurements required by 180 NAC 7-073.01 in accordance with published protocols accepted by nationally recognized bodies.

7-073.05 A licensee must mathematically correct the outputs determined in 180 NAC 7-073.02, item 1, for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.

7-073.06 Full calibration measurements required by 180 NAC 7-073.01 and physical decay corrections required by 180 NAC 7-073.05 must be performed by a authorized medical physicist.

7-073.07 A licensee must maintain a record of each calibration in accordance with 180 NAC 7-108.

7-074 FULL CALIBRATION MEASUREMENTS ON REMOTE AFTERLOADER UNITS

7-074.01 A licensee authorized to use a remote afterloader unit for medical use must perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

    a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
    b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
4. At intervals not exceeding one year for low dose-rate remote afterloader units.

7-074.02 To satisfy the requirement of 7-074.01, full calibration measurements must include, as applicable, determination of:

1. The output within ± 5%;
2. Source positioning accuracy to within ±1 millimeter;
3. Source retraction with backup battery upon power failure;
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

7-074.03 In addition to the requirements for full calibration for low dose-rate remote afterloader units in 180 NAC 7-074.02, a licensee must perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one calendar quarter.

7-074.04 A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output.

7-074.05 A licensee must make full calibration measurements required by 180 NAC 7-074.01 in accordance with published protocols accepted by nationally recognized bodies.

7-074.06 For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with180 NAC 7-074.01 through 7-074.05.

7-074.07 A licensee must mathematically correct the outputs determined in 180 NAC 7-074.02, item 1 for physical decay at intervals consistent with one percent physical decay.

7-074.08 Full calibration measurements required by 180 NAC 7-074.01 and physical decay corrections required by 180 NAC 7-074.07 must be performed by the authorized medical physicist.

7-074.09 A licensee must retain a record of each calibration in accordance with 180 NAC 7-108.

7-075 FULL CALIBRATION MEASUREMENTS ON GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-075.01 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

    a. Whenever spot-check measurements indicate that the output differs by +/- 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
    b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
    c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

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

7-075.02 To satisfy the requirement of 180 NAC 7-075.01, full calibration measurements must include determination of:

1. The output within ±3%;
2. Relative helmet factors; (to verify that the helmet material provides the required shielding to the patient);
3. Isocenter coincidence; (to confirm the centering accuracy of the radiation beam relative to the alignment helmet openings);
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity; (to determine the rotational center of the source relative to the alignment helmet openings);
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches; (to determine if the switches terminate the radiation beam when);

9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

7-075.03 A licensee must use the dosimetry system described in 180 NAC 7-072.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 180 NAC 7-075.02, item 1 may be made using a dosimetry system that indicates relative dose rates.

7-075.04 A licensee must make full calibration measurements required by 180 NAC 7-075.01 in accordance with published protocols accepted by nationally recognized bodies.

7-075.05 A licensee must mathematically correct the outputs determined in 180 NAC 7-075.02, item 1 at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.

7-075.06 Full calibration measurements required by 180 NAC 7-075.01 and physical decay corrections required by 180 NAC 7-075.05 must be performed by the authorized medical physicist.

7-075.07 A licensee must retain a record of each calibration in accordance with 180 NAC 7-108.

7-076 PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS

7-076.01 A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02; and
6. The difference between the measurement made in 180 NAC 7-076.01, item 5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

7-076.02 A licensee must perform measurements required by 180 NAC 7-076.01 in accordance with written procedures established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot-check measurements.

7-076.03 A licensee must have the authorized medical physicist review and sign the results

of each spot-check within 15 days. The authorized medical physicist must notify the licensee within 10 days in writing of the results of each spot-check.

7-076.04 A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

7-076.05 If the results of the checks required in 180 NAC 7-076.02 and 7-076.04 indicate the malfunction of any system, a licensee must 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.

7-076.06 A licensee must retain a record of each spot-check required by 180 NAC 7-076.01 and 7-076.04 and in accordance with 180 NAC 7-109.

7-077 PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS

7-077.01 A licensee authorized to use a remote afterloader unit for medical use must perform spot-checks of each remote afterloader facility and on each unit:

1. At the beginning of each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;
2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and
3. After each source installation.

7-077.02 The licensee must have the authorized medical physicist establish written procedures for performing the spot-checks required in 180 NAC 7-077.01. The authorized medical physicist need not actually perform the spot-check measurements.

7-077.03 A licensee must have the authorized medical physicist review and sign the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee within 10 days in writing of the results of each spot-check.

7-077.04 To satisfy the requirements of 180 NAC 7-077.01, spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
4. Radiological emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

7-077.05 If the results of the checks required in 180 NAC 7-077.04 indicate the malfunction of any system, a licensee must 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.

7-077.06 A licensee must retain a record of each check required by 180 NAC 7-077.04 in accordance with 180 NAC 7-110.

7-078 PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-078.01 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

7-078.02 The licensee must have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in 180 NAC 7-078.01; and
2. Review and sign the results of each spot-check required by 180 NAC 7-078.01 within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist must notify the licensee within 10 days in writing of the results of the spot check.

7-078.03 To satisfy the requirements of 180 NAC 7-078.01, item 1, spot-checks must, at a minimum:

1. Assure proper operation of:

    a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
    b. Helmet microswitches;

c. Emergency timing circuits; and
d. Stereotactic frames and localizing devices (trunnions).

2. Determine:

a. The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02;
b, The difference between the measurement made in 180 NAC 7-078.03, item b. and the anticipated output, expressed as a percentage of the anticipated output, (that is, the value obtained at last full calibration corrected mathematically for physical decay);
c. Source output against computer calculation;
d. Timer accuracy and linearity over the range of use;
e. On-off error; and
f. Trunnion centricity.

7-078.04 To satisfy the requirements of 180 NAC 7-078.01, item 2 and 3, spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

7-078.05 A licensee must arrange for the repair of any system identified in 180 NAC 7-078.03 that is not operating properly.

7-078.06 If the results of the checks required in 180 NAC 7-078.04 indicate the malfunction of any system, a licensee must 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.

7-078.07 A licensee must retain a record of each check required by 180 NAC 7-078.03 and 7-078.04 and in accordance with 180 NAC 7-111.

7-079 ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS

7-079.01 A licensee providing mobile remote afterloader service must:

1. Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
2. Account for all sources before departure from a client's address of use.

7-079.02 In addition to the periodic spot-checks required by 180 NAC 7-077 a licensee authorized to use mobile afterloaders for medical use will perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
5. Radiation monitors used to indicate room exposures;
6. Source positioning (accuracy); and
7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

7-079.03 In addition to the requirements for checks 180 NAC 7-079.02, a licensee must ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

7-079.04 If the results of the checks required in 180 NAC 7-079.02 indicate the malfunction of any system, a licensee must 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.

7-079.05 A licensee must retain a record of each check required by 180 NAC 7-079.02 in accordance with 180 NAC 7-112.

7-080 RADIATION SURVEYS

7-080.01 In addition to the survey requirement in 180 NAC 4-021, a person licensed to possess or a use remote afterloader, teletherapy or gamma stereotactic radiosurgery unit must perform surveys of the device and ensure the results of the surveys from the surface of the main source safe, with the sources in the shielded position, do not exceed the maximum and average radiation levels listed in the sealed source and device registry.

7-080.02 The licensee must make the survey required by 180 NAC 7-080.01 upon 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).

7-080.03 A licensee must retain a record of the radiation surveys required by 180 NAC 7-080.01 in accordance with 180 NAC 7-113.

7-081 FIVE-YEAR INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-081.01 A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

7-081.02 This inspection and servicing must only be performed by persons specifically licensed to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

7-081.03 A licensee must maintain a record of the inspection and servicing in accordance with 180 NAC 7-114.

7-082 THERAPY-RELATED COMPUTER SYSTEMS: The licensee must perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

7-082.01 The source-specific input parameters required by the dose calculation algorithm;

7-082.02 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7-082.03 The accuracy of isodose plots and graphic displays;

7-082.04 The accuracy of the software used to determine radioactive source positions from radiographic images; and

7-082.05 The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

7-083 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μSv (0.1 mrem) per hour to 1,000 μSv (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 μSv(1 mrem) per hour to 10 mSv (1000 mrems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-030.

7-084 TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS: Except as provided in 180 NAC 7-026, the licensee must require an authorized user of a sealed source for a use authorized under 180 NAC 7-067 to be a physician who:

7-084.01 Is certified by a medical specialty board whose certification process has been recognized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC) and who meets the requirements of 180 NAC 7-084.03 and 7-084.04.

(The names of board certifications which have been recognized the Department, an Agreement State or the U.S. Nuclear Regulatory Commission will be posed on the NRC's Web page.) To be recognized, a specialty board must require all candidates for certification to:

1. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

7-084.02 The physician:

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

   a. 200 hours of classroom and laboratory training in the following areas:

      (1) Radiation physics and instrumentation;
      (2) Radiation protection;
      (3) Mathematics pertaining to the use and measurement of radioactivity; and
      (4) Radiation biology; and

   b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-084 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical institution, involving:

      (1) Reviewing full calibration measurements and periodic spot-checks;
      (2) Preparing treatment plans and calculating treatment doses and times;
      (3) Using administrative controls to prevent a misadministration involving the use of radioactive material;
      (4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
      (5) Checking and using survey meters; and
      (6) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation

therapy, under an authorized user who meets the requirements in 180 NAC 7-026, 7-084, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 180 NAC 7-084.02, item 1.b.; and

3. Meets the requirements of 180 NAC 7-084.03 and 7-084.04.

7-084.03 Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-084.01, item 1 or 7-084.02, item 1 and 2, and 7-084.04 has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-084 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

7-084.04 Has received training in device operation, safety procedures, and clinical use of the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

7-085 OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL: A licensee may use radioactive material or radiation sources approved for medical use which is not specifically addressed in 180 NAC 7:

7-085.01 The applicant or licensee has submitted the information required by 180 NAC 7-008.02 through 7-008.04; and

7-085.02 The applicant or licensee has received written approval from the U.S. Nuclear Regulatory Commission or Agreement State in a license and uses the material in accordance with the regulations and specific conditions the U.S. Nuclear Regulatory Commission or Agreement State considers necessary for the medical use of the material.

RECORDS

7-086 RECORDS OF AUTHORITY AND RESPONSIBILITIES FOR RADIATION PROTECTION PROGRAMS

7-086.01 A licensee must retain a record of actions taken by the licensee's management in accordance with 180 NAC 7-015.02 and 7-015.03 for five years. The record must include a summary of the actions taken and a signature of licensee management.

7-086.02 The licensee must retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 180 NAC 7-015.06, and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 180 NAC 7-015.04. The record must include the signature of the Radiation Safety Officer and licensee management.

7-086.03 The minutes of each Radiation Safety Committee meeting held in accordance with 180 NAC 7-015.09 must include:

1. The date of the meeting;
2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

7-087 RECORDS OF RADIATION PROTECTION PROGRAM CHANGES: A licensee must retain a record of each radiation protection program made in accordance with 180 NAC 7-016.01 for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

7-088 RECORDS OF WRITTEN DIRECTIVES: A licensee must retain a copy of each written directive as required by 180 NAC 7-019 for three years.

7-089 RECORDS OF MISADMINISTRATION: A licensee must retain a record of misadministration reported in accordance with 180 NAC 7-115 for three years. The record must contain the licensee's name; name of the individual involved; the social security number or other identification number; if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any taken, or planned, to prevent recurrence; and whether the licensee notified the individual (or the individual's responsible relative or guardian): and, if not, whether such failure to notify was based on guidance from the referring physician.

7-090 RECORDS OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD: A licensee must retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 180 NAC 7-117 for three years. The record must contain the licensee's name; name of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken or planned, to prevent recurrence; and whether the licensee notified the

pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

7-091 RECORDS OF CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTVITY OF UNSEALED RADIOACTIVE MATERIAL: A licensee must maintain a record of instrument calibrations required by 180 NAC 7-029 for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

7-092 RECORDS OF RADIATION SURVEY INSTRUMENT CALIBRATIONS: A licensee must maintain a record of radiation survey instrument calibration required by 180 NAC 7-030 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

7-093 RECORDS OF DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE: A licensee must maintain a record of dosage determinations required by 180 NAC 7-031 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

7-094 RECORDS OF INVENTORY OF SEALED SOURCES AND BRACHYTHERAPY SOURCES: A licensee must retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 180 NAC 7-033.04 for three years. The inventory records must include the model number of each source, the serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the test.

7-095 RECORDS OF ~~LEAKS TESTS AND~~ SURVEYS FOR AMBIENT RADIATION EXPOSURE RATE AND CONTAMINATION: A licensee must retain a record of each survey required by 180 NAC 7–036 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

7-096 RECORDS OF THE RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS CONTAINING RADIOACTIVE MATERIAL

7-096.01 A licensee must retain a record signed by the authorized user, or the basis for authorizing the release of an individual, for three years after the date of release.

7-096.02 A licensee must retain a record, for three years after the date of release, that the instructions required by 180 NAC 7-037.02 were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

7-096.03 A licensee must retain a record, for three years after the date of release, that the instructions required by 180 NAC 7-037.02 were provided to a breast-feeding woman.

7-097 RECORDS OF ADMINISTRATIVE AND TECHNICAL REQUIREMENTS THAT APPLY TO THE PROVISION OF MOBILE SERVICES

7-097.01 A licensee must retain a copy of each letter that permits the use of radioactive material at a client's address, as required by 180 NAC 7-09.02, for three years after the last provision of service.

7-097.02 A licensee must retain the record of each survey required by 180 NAC 7-038.06, for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

7-098 RECORDS OF DECAY-IN-STORAGE: See 180 NAC 4-054.02.

7-099 RECORDS OF RADIONUCLIDE PURITY: A licensee must maintain a record of the radionuclide contaminant concentration tests required by 180 NAC 7-045.02 for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

7-100 RECORDS OF TRAINING: A licensee must maintain records of training required by 180 NAC 7-025 for three years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

7-101 RECORDS OF SAFETY INSTRUCTION AND TRAINING: A licensee must maintain a record of safety instructions required by 180 NAC 7-049, 7-058 and 7-070 for three years. The record must include a list of 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.

7-102 RECORDS OF SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS: A licensee must maintain a record of the surveys required by 180 NAC 7-056 and 7-068 for three years. Each record must include the date and the results of the survey, the specific survey instrument used, and the name of the individual who made the survey.

7-103 RECORDS OF BRACHYTHERAPY SOURCE INVENTORY

7-103.01 A licensee must maintain a record of brachytherapy source accountability required by 180 NAC 7-057 for three years.

7-103.02 For temporary implants, the record must include:

1 The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
2. The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

7-103.03 For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of sources permanently implanted in the patient or human research subject.

7-104 RECORDS OF CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES

7-104.01 A licensee must maintain a record of the calibrations of brachytherapy sources required by 180 NAC 7-060 for three years after the last use of the source. The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
3. The source output or activity;
4. The source positioning accuracy within the applicators; and
5. The signature of the authorized medical physicist.

7-105 RECORDS OF DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS

7-105.01 A licensee must maintain a record of the activity of a strontium-90 source required by 180 NAC 7-060 for the life of the source.

7-105.02 The record must include:

1. The date and initial activity of the source as determined under 180 NAC 7-060; and
2. For each decay calculation, the date and the source activity as determined under 180 NAC 7-060.

7-106 RECORDS OF INSTALLATION, MAINTENANCE, ADJUSTMENT, AND REPAIR: A licensee must retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 180

NAC 7-069 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

7-107 RECORDS OF DOSIMETRY EQUIPMENT

7-107.01 A licensee must retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 180 NAC 7-072 for the duration of the license.

7-107.02 For each calibration, intercomparison, or comparison, the record must include:

1. The date;
2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 180 NAC 7-072.01 and 7-072.02;
3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
4. The names of the individuals who performed the calibration, intercomparison, or comparison.

7-108 RECORDS OF TELETHERAPY, REMOTE AFTERLOADER, AND GAMMA STEREOTACTIC RADIOSURGERY FULL CALIBRATIONS

7-108.01 A licensee must maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by 180 NAC 7-073 through 7-075 for three years.

7-108.02 The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);
3. The results and an assessment of the full calibrations;
4. The results of the autoradiograph required for low dose-rate remote afterloader units; and
5. The signature of the authorized medical physicist who performed the full calibration.

7-109 RECORDS OF PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS

7-109.01 A licensee must retain a record of each periodic spot-check for teletherapy units required by 180 NAC 7-076 for three years.

7-109.02 The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7-110 RECORDS OF PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS

7-110.01 A licensee must retain a record of each spot-check for remote afterloader units required by 180 NAC 7-077 for three years.

7-110.02 The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7-111 RECORDS OF PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-111.01 A licensee must retain a record of each spot-check for gamma stereotactic radiosurgery units required by 180 NAC 7-078 for three years.

7-111.02 The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the gamma

stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

7-112 RECORDS OF ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS

7-112.01 A licensee must retain a record of each check for mobile remote afterloader units required by 180 NAC 7-079 for three years.

7-112.02 The record must include:

1. The date of the check;
2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
3. Notations accounting for all sources before the licensee departs from a facility;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and
5. The signature of the individual who performed the check.

7-113 RECORDS OF SURVEYS OF THERAPEUTIC TREATMENT UNITS

7-113.01 A licensee must maintain a record of radiation surveys of treatment units made in accordance with 180 NAC 7-080 for the duration of use of the unit.

7-113.02 The record must include:

1. The date of the measurements;
2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test.

7-114 RECORDS OF FIVE YEAR INSPECTIONS FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

7-114.01 A licensee must maintain a record of the five year inspections for teletherapy and gamma stereotactic radiosurgery units required by 180 NAC 7-081 for the duration of use of the unit.

7-114.02 The record must contain:

1. The inspector's radioactive materials license number;
2. The date of inspection;
3. The manufacturer's name and model number and serial number of both the treatment unit and source;
4. A list of components inspected and serviced, and the type of service; and
5. The signature of the inspector.

REPORTS

7-115 REPORT AND NOTIFICATION OF MISADMINISTRATION

7-115.01 Other than events that result from intervention by a patient or human research subject, a licensee must report any event in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

    a. The total dose delivered differs from the prescribed dose by 20% or more; or
    b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
    c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

    a. An administration of a wrong radioactive drug;
    b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;
    c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or
e. A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% 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).

7-115.02 A licensee must 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.

7-115.03 The licensee must notify the Department by telephone, no later than the next business day after the discovery of a misadministration.

7-115.04 The licensee must submit a written report to the Department within 15 days after discovery of the misadministration.

1. The written report must include:

a. The licensee's name;
b. The name of the prescribing physician;
c. A brief description of the event;
d. Why the event occurred;
e. The effect, if any, on the individual(s) who received the administration;
f. What actions, if any, have been taken or are planned to prevent recurrence; and
g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report can not contain the individual's name or any other information that could lead to identification of the individual.

7-115.05 The licensee must provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that s/he 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 must make the appropriate notifications 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 180 NAC

7-115.05, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must 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 must provide such a written description if requested.

7-115.06 Aside from the notification requirement, nothing in 180 NAC 7-115 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

7-115.07 A licensee must retain a record of a misadministration in accordance with 180 NAC 7-089. A copy of the record required under 180 NAC 7-089 must be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

7-116 RECORDS OF SUPERVISION AUDITS: A licensee must maintain a record of audits required by 180 NAC 7-018.01, item 4 for three years. The record must include a list of items audited, the date of the audit, the name of the supervised individual, and the name and signature of the authorized user conducting the audit.

7-117 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

7-117.01 A licensee must report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

7-117.02 A licensee must report any dose to a nursing child that was not specifically approved, in advance, by the authorized user; that is a result of an administration of radioactive material to a breast-feeding individual that:

1. Is greater than 5 mSv (500 mrem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

7-117.03 The licensee must 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 180 NAC 7-117.01 or 7-117.02.

7-117.04 The licensee must 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 180 NAC 7-117.01 or 7-117.02.

1. The written report must include:

a. The licensee's name;
b. The name of the prescribing physician;
c. A brief description of the event;
d. Why the event occurred;
e. The effect, if any, on the embryo/fetus or the nursing child;
f. What actions, if any, have been taken or are planned to prevent recurrence; and
g. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report can not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

7-117.05 The licensee must 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 in 180 NAC 7-117.01 and 7-117.02, unless the referring physician personally informs the licensee either that s/he 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 must 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 180 NAC 7-117.05, 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 must 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 must provide such a written description if requested.

7-117.06 A licensee must retain a record of a dose to an embryo/fetus or a nursing child in accordance with 180 NAC 7-090. A copy of the record required under 180 NAC 7-090 must be provided to the referring physician, if other than the licensee, within 15 days after the discovery of the event.

7-118 REPORTS OF LEAKING SOURCES: A licensee must file a report within 5 days if a leak test required by 180 NAC 7-033 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

7-119 NOTIFICATION OF DECEASED PATIENT OR HUMAN RESEARCH SUBJECTS CONTAINING RADIOACTIVE MATERIAL

7-119.01 The licensee must notify the Department by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 180 NAC 4-013 as a result of the deceased's body.

7-119.02 The licensee must submit a written report to the Department within 30 days after discovery that the patient or human research subject reference in 180 NAC 7-119.01 has died. The written report must include:

1. The licensee's name;
2. The date of death;
3. The radionuclide, chemical and physical form and calculated activity at time of death; and
4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 mSv (500 mrem).

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
RADIOLOGICAL HEALTH
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - Medical

INSTRUCTIONS - (Use additional sheets where necessary.)
Retain one copy for your files and submit original application to: Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Hospital, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

e-Mail Address:

1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)

(1) Permanent Address: _____

`

_____

City, State Zip +4: _____

(2) Temporary Job Sites Throughout Nebraska? Yes No

2. Person to Contact Regarding this Application

_____

Telephone #:_____

3. This is an application for:

New License

Amendment to License No._____

Renewal of License No._____

☐ **Table C-2 "Checklist for Items 4-6 of NRH -7" of Regulatory Guide 7.0 (RG 7.0) Appendix C is attached and completed for Items 4-6 of this application instead of completing the items on this form or equivalent pages.** (check if used and attached.) R**G 7.0 Revision** _____ **Date** _____

4. Individual User(s) (Check two)
☐ Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials is listed below. **OR**
☐ A Equivalent list is attached on 8½" x 11" paper

AND

☐ Complete a NRH-7A for each individual listed below.

First Name + Middle Initial	Last Name	Title	Nebraska Medical License #	Place a checkmark for each use of material in 180 NAC 7-						
				041	044	048	055	065	067	085

5. Radiation Safety

5.A. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer)
_____
Telephone #:_____
Complete a NRH-7A for the RSO.

5.B Radiation Safety Committee(If required by 180 NAC 7-015.08)
☐ A description of the Radiation Committee is attached.

Department Use Only

Date Received Stamp

6. Radioactive Material Data

6.A. Radioactive Material for Medical Use

(Can be completed on additional 8½" x 11" paper or use Appendix C of Regulatory Guide 7.0)

Radioactive Material (Elements and mass number)	**Chemical/Physical Form** (Make & Model if sealed source)	**Maximum Activity Requested** (Expressed as Curies, Millicuries, or Micorcuries)	**Use of Each Form** (If sealed source, also give Make and Model Number of the storage and/or device in which the sealed source will be stored and/or used)
Title 180 NAC 3-008.09			For In Vitro Studies
Title 180 NAC 7-041			
Title 180 NAC 7-044			
Title 180 NAC 7-048			
Title 180 NAC 7-055			
Title 180 NAC 7-065			
Title 180 NAC 7-067			
Title 180 NAC 7-085			

6.B. Radioactive Material for Uses not Listed in Item 6.a.

6.b.(1)Element and Mass Number	6.b.(2) Chemical or Physical Form (Make and Model if sealed source)	6.b.(3) Maximum Activity Requested (Expressed as Curies, Millicuries, or Microcuries)	6.b.(4) Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

6.C All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in 180 NAC 3-018 must provide evidence of financial assurance for decommissioning.

☐ **Table C-3 "Checklist for Items 7-9 of NRH -7" of Regulatory Guide 7.0 (RG 7.0) Appendix C is attached and completed for Items 7-9 of this application instead of completing the items on this form or equivalent pages.** (check if used and attached.) R**G 7.0 Revision _____ Date _____**

OR

The type and scope of information to be provided for items 7 through 9 is described in "Regulatory Guide 7.0 - Radioactive Material Guidance for Medical Use Programs" (RG 7.0)

The information required of the applicant can be submitted on separate sheets for each item. Identify the item number and date of the application in the lower right hand corner of each page OR the information can be submitted on the appropriate pages from the most recent revision of Regulatory Guide 7.0 (RG 7.0). Revision _____ Date_____. (Please indicate the most recent revision and date of RG 7.0 used to complete this application.)

7. FACILITIES AND EQUIPMENT

7.A. Facility Diagram (check two)
- ☐ Facility Diagrams are attached
- ☐ Facility Descriptions are attached

7.B. Instrumentation (check one)
- ☐ Part 1 of Appendix G of RG 7.0 is attached and will use Appendix G of RG 7.0; **OR**
- ☐ Part 1 of Appendix G of RG 7.0 is attached and Equivalent Procedures are attached

7.C. Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material (check one)
- ☐ Appendix H of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached **OR**
- ☐ Not applicable. (No unsealed radioactive material will be used.)

7.D. Therapy Unit – Calibration and Use (check one)
- ☐ Procedures are attached (For HDR, Gamma Stereotactic Radiosurgery Unit, Teletherapy or Brachytherapy Use) **OR**
- ☐ Not applicable.

7.E. Other Equipment and Facilities (check one)
- ☐ Appendix X is attached **OR**
- ☐ Not applicable.

8. Radiation Protection Program

8.A. Safety Procedures and Instructions (check one)
- ☐ Attached Safety Procedures and Instructions per 180 NAC 7-070 (For Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units) **OR**
- ☐ Not applicable

8.B. Safety Instructions for Individuals Working in or Frequenting Restricted Areas) (check one)
- ☐ Appendix I of R.G. 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.C. Operating and Emergency Procedures (check three)
- ☐ Attach Operating and Emergency procedures

AND
- ☐ Appendix J of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached and will be used

AND ONE OF THE FOLLOWING (Check one)
- ☐ Attachment 1 of Appendix J will be used **OR**
- ☐ Equivalent Attachment is attached and will be used

8.D. Safe Use of Unsealed Radioactive Materials (check one)
- ☐ Appendix K of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures and are attached and will be used; **OR**
- ☐ Not applicable

8.E. Radioactive Gases and Aerosol (e.g., Xenon-133) (check one)
- ☐ Appendix Y is attached; **OR**
- ☐ Equivalent Supporting Information and Calculations Attached **OR**
- ☐ Not applicable

8.F. Minimization of Contamination (check one)
- ☐ Attach a description of how facility design and procedures of operation will minimize contamination

8.G. Ordering and Receiving (check two)
- ☐ Attach Procedures for receipt and accountability; **AND**
- ☐ Appendix L of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.H. Opening Packages Containing Radioactive Material (check one)
- ☐ Appendix M of RG 7.0 will be used **OR**

- ☐ Equivalent Procedures are attached and will be used

8.I. ALARA (check one)
- ☐ Appendix Z of RG 7.0 is attached **OR**
- ☐ Equivalent Procedures are attached and will be used

8.J. Occupational Dose Dosimetry, Internal and External Exposure) (check one)
- ☐ Part 1 of Appendix N is attached

8.K. Area Surveys (check one)
- ☐ Appendix O of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.L. Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources (check one)
- ☐ Appendix AA of RG 7.0 is attached **OR**
- ☐ Not applicable

8.M. Procedures for Administrations when a Written Directive is Required (check one)
- ☐ Appendix P of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used **OR**
- ☐ Not applicable

8.N. Safety Procedures for Treatment When Patients are Hospitalized (check one)
- ☐ Procedures are attached **OR**
- ☐ Not applicable

8.O. Release of Patients or Human Research Subjects (check one)
- ☐ Appendix Q will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used **OR**
- ☐ Not applicable

8.P. Mobile Medical Service (check one)
- ☐ Procedures are attached (See Appendix E of RG 7.0) **OR**
- ☐ Not applicable

8.Q. Leak Tests (check one)
- ☐ Part 1 of Appendix R of RG 7.0 is attached and will use Appendix R of RG 7.0; **OR**
- ☐ Part 1 of Appendix R of RG 7.0 is attached and Equivalent Procedures are attached and will be used

NOTE: No response is required for the following items but will be examined during an inspection.

Public Dose, Audit Program, Sealed Source Inventory, Records of Dosage and Use of Brachytherapy Sources, Recordkeeping, Reporting and Transportation.

9. <u>Waste Management</u> (check one)
- ☐ Appendix W will be used.; **OR**
- ☐ Equivalent Procedures attached

10. . **CITIZENSHIP ATTESTATION**

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ _____

OR

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§ 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (Type or print first, middle, last)	Signature	Date

11.
CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services, Title 180, Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. I am authorized to make binding commitments and to sign official documents on the behalf of the applicant.

_____
Applicant Name From Item 1.a.

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

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Department of Health & Human Services
DHHS
NEBRASKA

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - MEDICAL
NRH - 7A
Medical Use Training and Experience and Preceptor Attestation
Part 1 - Training and Experience

Follow Regulatory Guide for NRH 7A "Medical Use Training & Experience and Preceptor Statement" when determining what information is needed for each type of medical use license.

Note: Description of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations in 180 NAC 7.

1. Name of Individual: _____

Address: _____

Telephone Number: _____ **FAX Number:** _____

E-Mail Address: _____

2. Is the individual a physician or pharmacist who is licensed to dispense drugs in the practice of medicine in Nebraska?

YES (If Yes, list the Nebraska Medical or Pharmacist License #) License #: _____

NO

3. Authorization

On a current license or permit (Provide a copy of the license or broadscope permit listing the current authorization)

The individual is identified on a license or permit as a:

Radiation Safety Officer for medical use licensee

Authorized Medical Physicist

Authorized Nuclear Pharmacist

Authorized User for _____ use(s).

The license or permit number _____.

The individual is seeking additional authorization, as a:

Radiation Safety Officer for medical use licensee

Authorized Medical Physicist

Authorized Nuclear Pharmacist

Authorized User for _____ use(s).

4. Certification

Specialty Board	Category	Month and Year Certified

5. Classroom and laboratory training

Description of Training	Location of training	Dates of Training	Clock Hours in Lecture or Laboratory

6. Work Experience

6.A. Work Experience with Radiation.

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

6.B. Supervised Clinical Experience (describe experience elements in 6.A.)

Isotope	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Radioactive Materials License Number	Date and/or Clock Hours of Experience

6.C. Training for Radiation Safety Officer, Medical Physicist, Authorized Use of sealed sources for diagnosis or Authorized User of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Training Element	Type of Training*	Locations and Dates

*Types of training may include supervised didactic, or vendor training.

6.D. Formal Training

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Material License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education and the Applicable Regulation)

7. One Year Full-Time Experience and/or Training

7.A. Radiation Safety Officer

YES
NA

Completed one year of full-time radiation safety experience (in areas identified in 6.A.) under the supervision of_____ the RSO of License No. _____.

7.B. Medical Physicist

YES
NA

Completed one year of full-time training (in areas identified in 6a) in medical physics under the supervision of _____ who meets the requirements of a authorized medical physicist or meets the requirements for Authorized Medical Physicist.

AND

YES
NA

Completed one year of full-time experience (at location providing radiation therapy services described and for topic identified in item 5.A.) for (specify use or device)_____ under the supervision of _____ who is meets the requirements for Authorized Medical Physicists (180 NAC 7-023 (specify use or device) _____.

8. Supervising Individual – Identification and Qualifications

The training and experience indicated above was obtained under the supervision of (*if more than one supervising individual is needed to meet requirements in 180 NAC 7, provide the following information for each):*

8.A. Name of Supervisor

_____

8.B. Supervisor is:

Authorized User
Authorized Medical Physicist
Radiation Safety Officer
Authorized Nuclear Pharmacist

8.C. The supervisor meets the requirements of 180 NAC 7-_____ for medical uses in 180 NAC 7-_____.

8.D. Authorized User on Radioactive Material License Number:

8.E. Licensee Name:
Licensee Address:

SUPPLEMENT A Medical Use Training and Experience and Preceptor Attestation
Part 2—Preceptor Attestation

Note: *The individual's preceptor must complete this part. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.*

9. Preceptor Attestation

9.A. I attest that _____(name of individual named in Item 1):

has satisfactorily completed the requirements in 180 NAC 7-_____, as documented in this application.

9.B. meets the requirements of 180 NAC 7-_____ for types of use, as documented in section(s)_____ of this form.

9.C. has achieved a level of competency and radiation safety knowledge sufficient to function independently as a: (check one)

Radiation Safety Officer for a medical use licensee

Authorized Medical Physicist

Authorized Nuclear Pharmacist

Authorized User for _____ uses.

9.D. I am a

Authorized User Authorized Medical Physicist

Radiation Safety Officer Authorized Nuclear Pharmacist

I meet the requirement of 180 NAC 7-_____ for medical uses in 180 NAC 7-_____.

9.E. Preceptor on Radioactive Material License #:	**9.F**. Licensee Name: Licensee Address:

9.G. Name of Preceptor (type or print clearly)	Signature --Preceptor	Date