

## **TITLE 180 - CONTROL OF RADIATION**

### **CHAPTER 7 - MEDICAL USE OF RADIOACTIVE MATERIAL**

Effective Date: 6/14/2023

**001. SCOPE AND AUTHORITY.** 180 Nebraska Administrative Code (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 180. The requirements and provisions of 180 NAC 1, 3, 4, 10, 13, 15, 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, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-3501 to 71-3520.

**002. DEFINITIONS.** As used in 180 NAC 7, the following definitions apply to this chapter:

002.01 ACCREDITED INSTITUTION. A teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

002.02 ADDRESS OF USE. The address of the building or buildings identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

002.03 AREA OF USE. The portion of an address of use set aside for the purpose of receiving, using, or storing radioactive material.

002.04 ASSOCIATE RADIATION SAFETY OFFICER (ARSO). An individual who:

- (A) Meets the requirements in 180 NAC 7-022 and 7-027; and
- (B) Is currently identified as an ARSO for the types of use of radioactive material for which the individual has been assigned duties and tasks by the RSO on:
  - (i) A specific medical use license issued by the Department, the U.S. Nuclear Regulatory Commission (NRC), or an Agreement State; or
  - (ii) A medical use permit issued by an U.S. Nuclear Regulatory Commission (NRC) master material licensee.

002.05 AUTHORIZED MEDICAL PHYSICIST. An individual who:

- (A) Meets the requirements in 180 NAC 7-023(A) and 7-027; or
- (B) Is identified as an authorized medical physicist or teletherapy physicist on a specific license or equivalent permit issued by the Department, NRC or Agreement State; or
- (C) Is identified as an authorized medical physicist on a permit issued by a Department, NRC, or Agreement State specific medical use license of

broad scope authorized to permit the use of radioactive material.

002.06 AUTHORIZED NUCLEAR PHARMACIST. A pharmacist who:

- (A) Meets the requirements of 180 NAC 7-024.01 and 7-027; or
- (B) 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, NRC or Agreement State; or
- (C) Is identified as an authorized nuclear pharmacist on a permit issued by the Department, NRC or Agreement State specific medical use license of broad scope authorized to permit the use of radioactive material.

002.07 AUTHORIZED USER. A physician, dentist, or podiatrist who:

- (A) Meets the requirements in 180 NAC 7-027 and 7-043(A), 7-047.01, 7-052.(A), 7-053.(A), 7-054.(A), 7-063.(A), 7-066.(A) or 7-084.(A); or
- (B) Is identified as an authorized user on a specific license or equivalent permit issued by the Department, NRC or Agreement State; or
- (C) Is identified as an authorized user on a permit issued by an Department, NRC or Agreement State specific license of broad scope authorized to permit the medical use of radioactive material.

002.08 BRACHYTHERAPY. A method of radiation therapy where 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.

002.09 BRACHYTHERAPY SOURCE. A radioactive source or a manufacturer-assembled source train or a combination of these sources designed to deliver a therapeutic dose within a distance of a few centimeters.

002.10 CLIENT'S ADDRESS. The address of use or a temporary job site for the purpose of providing mobile medical service according to 180 NAC 7-038.

002.11 DEDICATED CHECK SOURCE. A radioactive source used to assure the consistent response of a radiation detection or measurement device over several months or years.

002.12 DIAGNOSTIC CLINICAL PROCEDURES MANUAL. 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.

002.13 HIGH DOSE-RATE (HDR) REMOTE AFTERLOADER. A device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

002.14 LOW DOSE-RATE (LDR) REMOTE AFTERLOADER. A device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

002.15 MANAGEMENT. The individual having the authority to manage, direct, or administer the licensee's activities, or that persons' designee or designees.

002.16 MANUAL BRACHYTHERAPY. A type of therapy where the brachytherapy sources are manually applied or inserted.

002.17 MEDICAL INSTITUTION. An organization where several medical disciplines are practiced.

002.18 MEDICAL USE. The intentional internal or external administration of radioactive material, or radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

002.19 MEDIUM DOSE-RATE (MDR) REMOTE AFTERLOADER. A brachytherapy device that remotely delivers a dose rate of greater than 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.

002.20 MISADMINISTRATION. An event that meets the criteria in 180 NAC 7-115.

002.21 MOBILE MEDICINE SERVICE. The transportation of radioactive material or its medical use at the client's address.

002.22 NUCLEAR MEDICINE TECHNOLOGIST. 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.

002.23 NUCLEAR MEDICINE TECHNOLOGY. 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.

002.24 OPHTHALMIC PHYSICIST. An individual who:

(A) Meets the requirements in 180 NAC 7-060.05 and 180 NAC 7-027; and

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

(i) Specific medical use license issued by the Department, NRC or an Agreement State;

(ii) Permit issued by a Department, NRC or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a NRC master material licensee; or

(iv) Permit issued by a NRC master material licensee broad scope medical use permittee.

002.25 OUTPUT. 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.

002.26 PATIENT INTERVENTION. Actions by the patient or human research subject, whether intentional or unintentional, dislodging or removing treatment devices or prematurely terminating the administration.

002.27 PRECEPTOR. An individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, authorized medical physicist, authorized nuclear pharmacist, nuclear medicine technologist, radiation therapy technologist, RSO, or ARSO.

002.28 PRESCRIBED DOSAGE. A specified activity or range of activity of radioactive drug as documented:

- (A) In a written directive as specified in 180 NAC 7-019; or
- (B) According to the directions of the authorized user for procedures performed per 180 NAC 7-041, 7-044 and 7-048.

002.29 PRESCRIBED DOSE. A prescribed dose means for:

- (A) Gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (B) Teletherapy, the total dose and dose per fraction as documented in the written directive;
- (C) Manual brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive; or
- (D) Remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

002.30 PULSED DOSE-RATE (PDR) REMOTE AFTERLOADER. A special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but is:

- (A) Approximately one-tenth of the activity of typical HDR remote afterloader sources; and
- (B) Used to simulate the radiobiology of a LDR treatment by inserting the source for a given fraction of each hour.

002.31 RADIATION SAFETY OFFICER (RSO). An individual who:

- (A) Meets the requirements in 180 NAC 7-022(A) and 7-026;
- (B) Is identified as RSO on an NRC or Agreement State license or other equivalent permit or license recognized by the Department for similar types and uses of radioactive material.

002.32 RADIATION THERAPIST. 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.

002.33 RADIATION THERAPY TECHNOLOGY. The science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

002.34 RADIOACTIVE DRUG. 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.

002.35 SEALED SOURCE AND DEVICE REGISTRY. A national registry that contains all the registration certificates maintained by the NRC that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

002.36 STEREOTACTIC RADIOSURGERY. The use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

002.37 STRUCTURED EDUCATION PROGRAM. An educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

002.38 TELETHERAPY. A method of radiation therapy where collimated gamma rays are delivered at a distance from the patient or human research subject.

002.39 TEMPORARY JOB SITE. A location where mobile medical services are conducted other than any location of use authorized on the license.

002.40 THERAPEUTIC DOSAGE. A radiation dosage of unsealed radioactive material intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

002.41 THERAPEUTIC DOSE. A radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

002.42 TREATMENT SITE. An anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

002.43 TYPE OF USE. The use of radioactive material as specified in 180 NAC 7-041, 7-044, 7-048, 7-055, 7-065, 7-067 or 7-085.

002.44 UNIT DOSAGE. A dosage that is:

- (A) Obtained or prepared according to the regulations for uses described in 180 NAC 7-041, 7-044, or 7-048; and
- (B) 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.

002.45 WRITTEN DIRECTIVE. 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.

**003. MAINTENANCE OF RECORDS.** Each record required by 180 NAC 7 must be an original, electronic, microform, or reproduced copy, authenticated by authorized personnel, and capable of producing legible, accurate, and complete records, throughout the retention period specified by Title 180. Records, letters, drawings, specifications, must include all pertinent information, stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

**004. PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS.**  
Requirements for research involving human subjects are as follows:

- (A) Research must be conducted, funded, supported, or regulated by a Federal agency that 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" according to the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;
- (B) Research involving human subjects authorized in 180 NAC 7-004 will be conducted using radioactive material authorized for medical use in the license; and
- (C) Nothing in 180 NAC 7-004 relieves the licensee from complying with the requirements in 180 NAC 7.

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

**006. IMPLEMENTATION.**

006.01 EFFECTIVE DATES. A licensee must implement the provisions in 180 NAC 7, with the exception of requirements listed in 180 NAC 7-006.02.

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

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

006.04 EXEMPT LICENSE CONDITIONS. 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.

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

006.06 COMPLIANCE. 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.

**007. LICENSE REQUIRED.** A person may manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use according to a specific license issued by the Department, NRC, or an Agreement State, or as allowed by 180 NAC 7-007. An individual may:

- (A) Receive, possess, use, or transfer radioactive material according to 180 NAC 7 under the supervision of an authorized user as provided in 180 NAC 7-018, unless prohibited by license condition; or
- (B) Prepare unsealed radioactive material for medical use according to 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.

## **008. APPLICATION FOR LICENSE, AMENDMENT, OR RENEWAL.**

008.01 SIGNATURE. An application for a license, amendment, or renewal must be signed by the applicant's or licensee's management.

008.02 LICENSE APPLICATION. An application for a new license or license renewal 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 submitting an original Form NRH-7 "Application for Radioactive Material License - Medical" provided by the Department.

008.03 LICENSE AMENDMENT. A request for a license amendment must be submitted as an original in letter format.

008.04 SUPPLEMENTAL INFORMATION. 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 not addressed in 180 NAC 7-001 through 7-040, as well as any specific information on:

- (A) Radiation safety precautions and instructions;
- (B) Training and experience of proposed users;
- (C) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
- (D) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

008.05 REQUEST FOR ADDITIONAL INFORMATION. An applicant or licensee must also provide any other information requested by the Department in its review of the application.

008.06 TYPE A SPECIFIC LICENSE OF BROAD SCOPE. An applicant that satisfies the requirements specified in 180 NAC 3-013.02 may apply for a Type A specific license of broad scope.

## **009. MOBILE MEDICAL SERVICE ADMINISTRATIVE REQUIREMENTS.**

009.01 LICENSURE. 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.

009.02 LETTERS OF AUTHORITY AND RESPONSIBILITY. 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 and clearly outlines the authority and responsibility of 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.

009.03 DELIVERY OF RADIOACTIVE MATERIAL DIRECTLY TO THE CLIENT. A mobile medical service must not have radioactive material delivered directly from the manufacturer or 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.

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

009.05 LETTER RETENTION. A licensee providing mobile medical services must retain the letter required in 180 NAC 7-009.02 according to 180 NAC 7-097.

009.06 DOCUMENT MAINTENANCE. A mobile medical service licensee must, at a minimum, maintain the following documents on each mobile unit:

- (A) The current operating and emergency procedures;
- (B) Copy of the license;

- (C) Copies of the letter required by 180 NAC 7-009.02;
- (D) Current calibration records for each survey instrument, diagnostic equipment, and dose calibration systems in use;
- (E) Quality control tests and records of quality control required by 180 NAC 7-028; and
- (F) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

**009.07 RECORDS.** 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:

- (A) A single address of use:
  - (i) Identified as the records retention location; and
  - (ii) Staffed at all reasonable hours by individual or individuals authorized to provide the Department with access for purposes of inspection; or
- (B) On the mobile unit:
  - (i) Identified in the license; and
  - (ii) Whose current client's address schedule and location is reported to the Department.

**010. LICENSE AMENDMENTS.** A licensee must apply for and receive a license amendment before:

- (A) Receiving, preparing, or using radioactive material for a type of use permitted under 180 NAC 7-007, but not authorized on the licensee's current license issued under 180 NAC 7;
- (B) Permitting anyone to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist under the license, other than an individual who is:
  - (i) An authorized user, who meets the requirements in 180 NAC 7-027 and 7-043(A), 7-047.01, 7-051(A), 7-052(A), 7-053(A), 7-063(A), 7-066(A), and 7-084(A);
  - (ii) An authorized nuclear pharmacist, who meets the requirements in 180 NAC 7-024 and 7-027;
  - (iii) An authorized medical physicist, an individual who meets the requirements in 180 NAC 7-027 and 7-023(A) and 7-023(C);
  - (iv) Identified as an authorized user, authorized nuclear pharmacist or authorized medical physicist, or an ophthalmic physicist;
    - (1) On an NRC 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; or
    - (2) On a permit by an NRC or Agreement State specific license of broad scope that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively;

- (C) Changing an RSO or ARSO, other than as provided in 180 NAC 7-015.05;
- (D) Receiving radioactive material in excess of the amount or in a different physical or chemical form, than is authorized on the license;
- (E) Adding to or changing the areas of use identified in the application or on the license;
- (F) Changing the address or addresses of use identified in the application or on the license;
- (G) Changing statements, representations, and procedures that are incorporated into the license; and
- (H) Releasing licensed facilities for unrestricted use.

## **011. NOTIFICATIONS.**

**011.01 DOCUMENTATION.** A licensee must provide to the Department a copy of the board certification, the NRC or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of a broad scope, or the permit issued by an NRC 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 NRC and for each individual no later than thirty days after the date the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist according to 180 NAC 7-010, (B). For individuals permitted to work under 180 NAC 7-010, (B) items within the same thirty day time frame, the licensee must also provide as appropriate, verification of completion of:

- (A) Any additional case experience required in 180 NAC 7-051(B)(i)(2)(f) for an authorized user under 180 NAC 7-048;
- (B) Any additional training required in 180 NAC 7-084(C) for an authorized user under 180 NAC 7-067; and
- (C) Any additional training required in 180 NAC 7-023(C) for an authorized medical physicist.

**011.02 NOTIFICATION.** A licensee must notify the Department, in writing, no later than thirty days after:

- (A) An authorized user, an authorized nuclear pharmacist, RSO, ophthalmic physicist, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
- (B) The licensee's mailing address changes; or
- (C) 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.

**011.03 DOCUMENT MAILING ADDRESS.** The licensee must send the documents required in 180 NAC 7-011 to the appropriate address identified

in 180 NAC 1-012.

**012. TYPE A SPECIFIC LICENSE OF BROAD SCOPE EXEMPTIONS.** A licensee possessing a Type A specific license of broad scope for medical use issued under 180 NAC 3-013 is exempt from the provisions of:

- (A) 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;
- (B) 180 NAC 7-010.02 regarding the need to file an amendment before permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license;
- (C) 180 NAC 7-010.05 regarding additions to or changes in the areas of use at the addresses specified in the license;
- (D) 180 NAC 7-011.01 regarding notification to the Department for new authorized users, authorized nuclear pharmacists, ophthalmic physicists, and authorized medical physicists; and
- (E) 180 NAC 7-021, (A) regarding supplier for sealed sources.

**013. LICENSE APPLICATION.** The applicant for a license for:

- (A) Medical use of radioactive material must:
  - (i) File NRH-7 "Application for Radioactive Material License – Medical" according to instructions in 180 NAC 7-008;
  - (ii) Pay any applicable fee as provided in 180 NAC 18;
  - (iii) Meet the requirements of 180 NAC 3; and
  - (iv) Establish that they are equipped and committed to observe the safety standards established by the Department in Title 180 for the protection of public health and safety.
- (B) Mobile medical service must:
  - (i) Meet the requirements in 180 NAC 7-013, (A); and
  - (ii) Demonstrate individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment according to 180 NAC 7-037.

**014. SPECIFIC EXEMPTIONS.** The Department may, upon application or upon its own initiative, grant such exemptions from the requirements of 180 NAC 7 as allowed by Neb. Rev. Stat. § 71-3507.

**015. RADIATION PROTECTION PROGRAM.**

015.01 NOTICE TO WORKERS. The licensee's program must include notice to workers of the program's existence and workers responsibility to help keep dose equivalents As Low As Reasonably Achievable (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 licensees make every reasonable effort to maintain individual and collective occupational

doses ALARA.

015.02 ALARA PROGRAM WRITTEN DESCRIPTION RETENTION. The licensee must retain a current written description of the ALARA program for the duration of the license. The written description must include:

- (A) A commitment by management to keep occupational doses as low as reasonably achievable;
- (B) A requirement that the RSO brief management once each year on the radiation safety program; and
- (C) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the RSO of the cause of the exposure and a consideration of possible actions taken to reduce the probability of recurrence.

015.03 WRITTEN APPROVAL. In addition to the radiation protection program requirements of 180 NAC 4-004, before submitting to the Department, a licensee's management must approve in writing any requests for a license application, renewal, or amendment for:

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

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

015.05 TEMPORARY RADIATION SAFETY OFFICER. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be an RSO to function as a temporary RSO 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 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.

015.06 AUTHORITY, DUTIES AND RESPONSIBILITIES. A licensee must establish in writing the authority, duties, and responsibilities of the RSO.

015.07 PROVISIONS. A licensee must provide the RSO sufficient authority, organizational freedom, time, resources and management prerogative to:

- (A) Identify radiation safety problems;
- (B) Initiate, recommend, or provide corrective actions;
- (C) Stop unsafe operations; and
- (D) Verify implementation of corrective actions.

015.08 RADIATION SAFETY COMMITTEE. Licensees authorized for 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, must 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 RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO, and may include other members the licensee deems appropriate.

015.09 RADIATION SAFETY COMMITTEE MEETINGS. A licensee's radiation safety committee must meet as necessary, but at intervals not to exceed six months. The licensee must maintain minutes of each meeting according to 180 NAC 7-086.

015.10 RECORD OF ACTIONS. A licensee must retain a record of actions taken under 180 NAC 7-015.01, 7-015.02 and 7-015.05 according to 180 NAC 7-086.

## **016. RADIATION PROTECTION PROGRAM CHANGES.**

016.01 REVISION LIMITATIONS. A licensee may revise its radiation protection program without Department approval if:

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

016.02 RECORDS. A licensee must retain a record of each change according to 180 NAC 7-087.

## **017. DUTIES OF AUTHORIZED USER AND AUTHORIZED MEDICAL PHYSICIST.**

017.01 AUTHORIZED USER. Only authorized users for the type of radioactive material used:

- (A) Prescribe the radiopharmaceutical dosage or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;
- (B) 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;
- (C) Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, according to 180 NAC 7-007 and 7-018; and
- (D) Perform the final interpretation of the results of tests, studies, or treatments.

017.02 AUTHORIZED MEDICAL PHYSICIST. Only authorized medical physicists may perform, as applicable:

- (A) Full calibration measurement as described in 180 NAC 7-073, 7-074, and 7-075; and
- (B) Radiation surveys as described in 180 NAC 7-080.

## **018. SUPERVISION.**

018.01 TRAINING, INSTRUCTIONS AND AUDITS. 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(A), must:

- (A) 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;
- (B) 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;
- (C) 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; and
- (D) 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(B) and physical observation of the individual performing the duties the authorized user has delegated to them.

018.02 PREPARATION OF RADIOACTIVE MATERIAL FOR MEDICAL USE. 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(B), must:

- (A) 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
- (B) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of 180 NAC 7, and license conditions.

**018.03 IMMEDIATE AVAILABILITY.** 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.

**018.04 RESPONSIBILITY.** 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.

## **019. WRITTEN DIRECTIVES.**

**019.01 DATE AND SIGNATURE.** 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 ( $\mu\text{Ci}$ )), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

- (A) 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.

**019.02 REQUIRED INFORMATION.** The written directive must contain the patient or human research subject's name and the following information:

- (A) For any administration of dosage of radioactive drug containing radioactive material: the radioactive drug containing radioactive material, dosage, and the route of administration;
- (B) For gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
- (C) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
- (D) For HDR remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;
- (E) For permanent implant brachytherapy:

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

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and date; or

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

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

(ii) 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; and the date.

019.03 WRITTEN REVISIONS. 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 unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(A) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

019.04 RETENTION. The licensee must retain a copy of the written directive according to 180 NAC 7-088.

## **020. PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE.**

020.01 WRITTEN PROCEDURES. For any administration requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that:

(A) The patient's or human research subject's identity is verified before each administration; and

(B) Each administration is according to the written directive.

020.02 VERIFICATION. 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:

(A) Verifying the identity of the patient or human research subject;

(B) Verifying that the specific details of the administration is according to the treatment plan, if applicable, and the written directive;

(C) Checking both manual and computer-generated dose calculations;

(D) 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;

- (E) Determining if a misadministration, as defined in 180 NAC 7-115, has occurred; and
- (F) Determining, for permanent implant brachytherapy, within sixty calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

**021. SUPPLIERS OF SEALED SOURCES OR DEVICES FOR MEDICAL USE.** A licensee may only use:

- (A) Sealed sources or devices initially manufactured, labeled, packaged, and distributed according to a license issued according to 180 NAC 3 or the equivalent regulations of the NRC or another Agreement State.
- (B) Teletherapy sources manufactured and distributed according to a license issued according to 180 NAC 3, or the equivalent regulations of the NRC or another Agreement State.

**022. TRAINING FOR RADIATION SAFETY OFFICER OR ASSOCIATE**

**RADIATION SAFETY OFFICER.** Other than provided in 180 NAC 7-026, the licensee must require an individual fulfilling the responsibilities of the RSO or an individual assigned duties and tasks as ARSO as provided in 180 NAC 7-015 to meet the following requirements:

- (A) The individual must be certified by a specialty board whose certification process has been recognized by the Department, an Agreement State or the NRC and who meets the requirements in 180 NAC 7-022(D). The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

(i) For bachelor's or graduate degrees:

- (1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
- (2) Have 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
- (3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(ii) For master's and doctor's degrees:

- (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 or supervised experience in medical physics:

(a) 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 NRC; or

(b) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 180 NAC 7-026, 7-047 or 7-051; and

(iii) Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(B) The individual must:

(i) Have completed a structured educational program consisting of both:

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(e) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an NRC or an Agreement State license or permit issued by an NRC master material licensee that authorizes similar type or types of use or uses of radioactive material. An ARSO may provide supervision for those areas for which the ARSO is authorized on an NRC or an Agreement State license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

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

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

(c) Securing and controlling radioactive material;

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

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

(f) Using emergency procedures to control radioactive material;

(g) Disposing of radioactive material; and

(ii) Obtain a written attestation, signed by a preceptor RSO or ARSO, who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as an RSO or as an ARSO. The written attestation must state that the individual has satisfactorily completed the requirements in 180 NAC 7-022(B)(i) and 180 NAC 7-022 (D), and is able to independently fulfill the radiation safety related duties as a radiation safety officer or as an associate radiation safety officer for medical use license; or

(C) The individual must:

- (i) Be a medical physicist certified by a specialty board whose certification process has been recognized by the Department, the NRC or an Agreement State in 180 NAC 7-023(A) 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 RSO or an ARSO, and who meets the requirement in 180 NAC 7-022(D); or
- (ii) Be an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the Department, the NRC or an Agreement State license, a permit issued by NRC master material licensee, a permit issued by the NRC or an Agreement State licensee of broad scope, or a permit issued by the NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the RSO or ARSO, and meets the requirements in 180 NAC 7-022(D); or
- (iii) Have experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the RSO and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material licensee. The individual must also meet the requirements in 180 NAC 7-022(D); and

(D) 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 supervised by a RSO, an ARSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user as appropriate, who is authorized for the type or types of use for which the licensee is seeking approval.

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

(A) An individual who is certified by a specialty board whose certification process has been recognized by the Department, the NRC or an Agreement State and who meets the requirements of 180 NAC 7-023(C). The names of board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

(i) 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;

(ii) Have two years of full-time practical training or supervision experience in medical physics:

(1) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Department, an Agreement State, or the NRC; or

(2) In a clinical radiation facility 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

(iii) Pass an examination, administered by diplomates 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

(B) An individual who:

(i) 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 or types 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:

(1) Performing sealed source leak tests and inventories;

(2) Performing decay corrections;

(3) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(4) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(ii) Has obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-023.02(B)(i) and 180 NAC 7-023(C), and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical

physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 180 NAC 7-023, 7-026 or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(C) Has training for the type or types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and 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 or types of use for which the individual is seeking authorization.

**024. TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST.** The licensee must require the authorized nuclear pharmacist to be a pharmacist who:

(A) Is certified by a specialty board whose certification process has been recognized by an Agreement State or the NRC. The names of the board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

- (i) Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education, previously named the American Council on Pharmaceutical Education, or have passed the Foreign Pharmacy Graduate Examination Committee examination;
- (ii) Hold a current, active license to practice pharmacy;
- (iii) Provide evidence of having acquired at least 4,000 hours of training or experience, or both in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and
- (iv) Pass an examination in nuclear pharmacy administered by diplomates 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

(B) Has completed all of the following requirements:

(i) 700 hours in a structured educational program consisting of both:

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

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of

- radioactivity;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology; and

(2) Supervised practical experience in nuclear pharmacy involving:

- (a) Shipping, receiving, and performing related radiation surveys;
- (b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- (c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (d) Using administrative controls to avoid misadministrations in the administration of radioactive material; and
- (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(ii) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements of 180 NAC 7-024(B) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

## **025. TRAINING AND TECHNICAL REQUIREMENT FOR NUCLEAR MEDICINE TECHNOLOGISTS AND RADIATION THERAPISTS.**

025.01 NUCLEAR MEDICINE TECHNOLOGY. The licensee must require an individual performing nuclear medicine technology under the supervision of an authorized user to be an individual who:

(A) Is certified in:

- (i) Nuclear Medicine by the Nuclear Medicine Technology Certification Board; or
- (ii) Nuclear Medicine by the American Registry of Radiologic Technologists (ARRT) with competency in Nuclear Medicine;

(B) Is board eligible to take the Nuclear Medicine Technology Certification Board or the ARRT with competency in Nuclear Medicine examination;

(C) 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

(D) Has training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:

- (i) 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;
- (5) Radiation biology; and
- (6) Imaging Technology;

(ii) 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; and
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(iii) 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; and

(iv) Has obtained written certification, signed by a preceptor authorized user the individual has satisfactorily completed the requirements of 180 NAC 7-025.01(D)(i) and (ii) and has achieved a level of radiation safety competency sufficient to independently function as a nuclear medicine technologist.

**025.02 RADIATION THERAPY.** The licensee must require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

- (A) Is certified in Radiation Therapy by the ARRT;
- (B) Be eligible to take the ARRT examination in Radiation Therapy;
- (C) 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, "Standards for Accredited Educational Program in Radiologic Sciences – Effective January 1, 2002", Joint Review Committee on Education in Radiologic Technology, January 1996; Revised 2001. This document is available for viewing at the Department of Health and Human Services, Office of Radiological Health, 301 Centennial Mall South, Lincoln, Nebraska 68509; or

(D) Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

(i) 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

(ii) 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

(iii) Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of 180 NAC 7-025.02 (D)(i) and (D)(ii) and has achieved a level of radiation safety competency sufficient to independently function as a radiation therapist.

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

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

026.01 LICENSE OR PERMIT. An individual identified on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as an RSO, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before the effective date of these regulations need not comply with the training requirements of 180 NAC 7-022 through 7-024, respectively, other than RSOs and authorized medical physicists identified in this paragraph must meet the training requirements in 180 NAC 7-022(D) or 7-023(C) as appropriate, for any material or uses for which they were not authorized prior to this date.

026.02 CERTIFICATION. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 180 NAC 7-022 to be identified as a radiation safety officer or as an associate on an NRC or an Agreement State license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

026.03 PRIOR CERTIFICATION. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 180 NAC 7-023, for those materials and uses that these individuals performed on or before October 24, 2005.

026.04 IDENTIFIED AS AN AUTHORIZED USER. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC, an Agreement State or the Department, a permit issued by an NRC master material licensee, a permit issued by an NRC, an Agreement State, or the Department broad scope licensee, or on a permit issued by an NRC master material license broad scope permittee before the effective date of these regulations, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements 180 NAC 7-041

through 7-084.

026.05 NOT IDENTIFIED AS AN AUTHORIZED USER. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or an Agreement State broad scope licensee, or a permit issued by an NRC master material broad scope license on or before October 24, 2005, need not comply with the training requirements for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

- (A) For uses authorized under 180 NAC 7-041 or 7-044 or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of xRadiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;
- (B) For uses authorized under 180 NAC 7-048, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;
- (C) For uses authorized under 180 NAC 7-055 or 7-067, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and
- (D) For uses authorized under 180 NAC 7-065, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

026.06 PRECEPTORS AND SUPERVISORS. 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.

**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.

**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 according to written procedures.

**029. POSSESSION, USE, AND CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTIVITY OF UNSEALED RADIOACTIVE MATERIAL.** To perform direct measurements according to 180 NAC 7-031, a licensee must:

(A) Possess and use instrumentation to measure the activity of unsealed radioactive material before administration to each patient or human research subject;

(B) Calibrate the instrumentation according to nationally recognized standards or the manufacturer's instructions. The calibrations must, at minimum and as appropriate to demonstrate proper operation of the instrument, test for:

- (i) Constancy;
- (ii) Linearity;
- (iii) Accuracy; and
- (iv) Geometry dependence; and

(C) Retain a record of each instrument test required by 180 NAC 7-029 according to 180 NAC 7-091.

### **030. CALIBRATION OF SURVEY INSTRUMENTS.**

**030.01 REQUIREMENTS.** A licensee must calibrate the survey instruments used to show compliance with 180 NAC 7 and 180 NAC 4 before first use, annually, and following any repair that affects the calibration. A licensee must:

(A) Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(B) Have each radiation survey instrument calibrated:

- (i) At energies appropriate for use and at annual intervals or after servicing instrument, other than battery changes;
- (ii) 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
- (iii) For dose rate instruments, so that an accuracy within plus or minus twenty percent of the true radiation dose rate can be demonstrated at each point checked; and

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

030.02 TOLERANCE. The licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than twenty percent.

030.03 SURVEY INSTRUMENT CHECK. 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.

030.04 RECORDS. A licensee must maintain a record of each survey instrument calibration according to 180 NAC 7-092.

### **031. DETERMINATION OF DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE.**

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

031.02 UNIT DOSAGE DETERMINATION. For unit dosages, this determination must be made by:

- (A) Direct measurement of radioactivity; or
- (B) A decay calculation, based on the activity or activity concentration determined by:
  - (i) A manufacturer or preparer licensed according to 180 NAC 3-014.10 or equivalent NRC or Agreement State requirements;
  - (ii) A Department, NRC, or Agreement State licensee for use in research according to a Radioactive Drug Research Committee-approved protocol or an Investigation New Drug (IND) protocol accepted by the FDA; or
  - (iii) A positron emission tomography (PET) radioactive drug producer licensed in 180 NAC 3-010.11 or equivalent NRC or Agreement State requirements.

031.034 OTHER THAN UNIT DOSAGE. For other than unit dosages, this determination must be made by:

- (A) Direct measurement of radioactivity;
- (B) Combination of measurement of radioactivity and mathematical calculations; or
- (C) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:
  - (i) A manufacturer or preparer licensed according to 180 NAC 3-014.10 or equivalent provision of the NRC or Agreement State; or
  - (ii) A PET radioactive drug producer licensed in 180 NAC 3-010.11 or equivalent NRC or Agreement State requirements.

031.04 DOSAGE RANGE. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage

by more than twenty percent.

031.05 RECORD RETENTION. A licensee must retain a record of the dosage determination required by 180 NAC 7 according to 180 NAC 7-093.

### **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:

(A) Sealed sources manufactured and distributed, or redistributed by persons specifically licensed according to 180 NAC 3 or equivalent provisions of the NRC, or Agreement State and that do not exceed 1.11 GBq (30 mCi) each;

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

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

(i) 7.4 MBq (200  $\mu$ Ci); or

(ii) 1000 times the quantities in Appendix B of 180 NAC 3; or

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

### **033. REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES.**

033.01 RADIATION SAFETY AND HANDLING INSTRUCTIONS. 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.

033.02 LEAK TESTING. A licensee in possession of a sealed source must:

(A) Test the source for leakage according to 180 NAC 1-011; and

(B) Test the source for leakage at intervals not to exceed six months or at intervals approved by the Department, another Agreement State, or the NRC in the Sealed Source and Device Registry.

033.03 REMOVABLE CONTAMINATION FINDING. If a leak test reveals the presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination, the licensee must:

(A) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired according to the requirements of 180 NAC 1-011.06 and 180 NAC 4; and

(B) File a report within five days of the leak test according to 180 NAC 7-118.

033.04 PHYSICAL INVENTORY. A licensee in possession of a sealed source or brachytherapy source, other than gamma stereotactic radiosurgery sources, must conduct a semi-annual physical inventory of all such sources. The

licensee must retain each inventory record according to 180 NAC 7-094.

**034. LABELING OF VIALS AND SYRINGES.** Each syringe and vial containing 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.

**035. VIAL AND SYRINGE SHIELDS.**

035.01 VIALS CONTAINING RADIOACTIVE DRUGS. A licensee must require each individual preparing or handling a vial containing a radioactive drug to keep the vial in a vial shield.

035.02 SYRINGES CONTAINING RADIOACTIVE MATERIAL. A licensee must:

- (A) Keep syringes containing radioactive material to be administered in a shield; and
- (B) Require each individual who prepares or administers radioactive drugs to use a syringe shield unless the use of the shield is contraindicated for that patient or human research subject.

**036. SURVEYS FOR AMBIENT RADIATION DOSE RATE AND CONTAMINATION.** A licensee must:

- (A) Survey with a radiation detection survey instrument:
  - (i) At the end of each day of use all areas where radioactive drugs are routinely prepared for use or administered; and
  - (ii) At least once each week all areas where radioactive drugs or radioactive wastes are stored;
- (B) Conduct the surveys required by 180 NAC 7-036 (A) so as to be able to measure dose rates as low as 1  $\mu$ Sv (0.1 mrem) per hour;
- (C) Establish dose rate action levels for the surveys required by 180 NAC 7-036 (A) and must require that the individual performing the survey to immediately notify the radiation safety officer if a dose rate exceeds the action level;
- (D) Survey for removable contamination:
  - (i) Once each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered, and
  - (ii) Once each week where unsealed radioactive materials are prepared for use or administered and where unsealed radioactive materials are stored;
- (E) Conduct the surveys required by 180 NAC 7-036 (D) so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm);
- (F) Establish removable contamination action levels for the surveys required by 180 NAC 7-036 (D) and must require that the individual performing the

survey to immediately notify the radiation safety officer if contamination exceeds the action level; and

(G) Retain a record of each survey according to 180 NAC 7-095.

### **037. RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS.**

037.01 TOTAL EFFECTIVE DOSE EQUIVALENT TO ANOTHER INDIVIDUAL. 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). NRC'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).

037.02 ORAL AND WRITTEN INSTRUCTIONS. 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 ALARA 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:

- (A) Guidance on the interruption or discontinuation of breast-feeding; and
- (B) Information on the potential consequences, if any, of failure to follow the guidance.

037.03 APPROVAL FOR PATIENT RELEASE. 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 an authorized user approved for the type of radioactive material use for which the patient being released has received.

037.04 RECORD OF BASIS FOR RELEASE. The licensee must maintain a record of the basis for authorizing the release of an individual according to 180 NAC 7-096.

037.05 RECORD OF INSTRUCTIONS PROVIDED TO BREASTFEEDING FEMALES. The licensee must maintain a record of instructions provided to a breast-feeding female according to 180 NAC 7-096.

037.06 NOTIFICATION. The licensee must notify the Department according to 180 NAC 7-119:

- (A) When they are aware a patient containing radioactive material and who was released according to 180 NAC 7-037 dies; and,
- (B) 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.

**038. MOBILE MEDICINE SERVICE TECHNICAL REQUIREMENTS.** A licensee providing mobile nuclear medicine services must:

- (A) Transport to each address of use only syringes or vials containing prepared drugs or radioactive materials intended for reconstitution of radioactive drug kits;
- (B) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- (C) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;
- (D) 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;
- (E) Check survey instruments for consistent response with a dedicated check source before use at each client's address;
- (F) 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;
- (G) 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
- (H) Retain a record of each survey required by 180 NAC 7-038, (F) according to 180 NAC 7-097.

**039. STORAGE AND CONTROL OF VOLATILES AND GASES.**

**039.01 VOLATILE RADIOACTIVE MATERIAL AND RADIOACTIVE GASES.** A licensee must store volatile radioactive material and radioactive gases in a radiation shield and container.

**039.02 MULTI-DOSE CONTAINER.** A licensee must store and use a multi-dose container in a properly functioning fume hood.

**039.03 AIRBORNE CONCENTRATIONS.** 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.

**039.04 VENTILATION.** 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.

**039.05 COLLECTION SYSTEM OPERATIONS CHECK.** 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.

**039.06 NEGATIVE PRESSURE ROOMS.** A licensee must only administer radioactive gases in rooms that are at negative pressure compared to

surrounding rooms.

**039.07 TIME AFTER RELEASE CALCULATION.** 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 180 NAC 4, Appendix 4-B. The calculation must be:

- (A) 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;
- (B) Posted at the area of use and require that, in the case of a gas spill, individuals evacuate the room until the posted time has elapsed; and
- (C) Recorded and retained for the duration of the license.

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

**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, prepared for medical use involving measurements of uptake, dilution, or excretion that is:

(A) Obtained from:

- (i) A manufacturer or preparer licensed according to 180 NAC 3-014.10 or equivalent NRC or Agreement State requirements; or
- (ii) A PET radioactive drug producer licensed under 180 NAC 3-010.11 or equivalent NRC or Agreement State requirements; or

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

- (i) An authorized nuclear pharmacist;
- (ii) 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(A)(ii) (7); or
- (iii) An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 180 NAC 7-041(B(i) or the physician who is authorized user in 180 NAC 7-041(Bii).

(C) Obtained from and prepared by an NRC or Agreement State licensee for use in research according to a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.

(D) Prepared by the licensee according to a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the FDA for use in research.

**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  $\mu$ Sv (0.1 mrem) per hour to 1000  $\mu$ Sv (100 mrem) per

hour. The instrument must be operable and calibrated according to 180 NAC 7-030.

**043. TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES.** Other than 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:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Department, NRC, or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

- (i) 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(C)(i) and (ii); and
- (ii) Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(B) Is an authorized user under 180 NAC 7-047 or 7-051 or equivalent NRC or Agreement State requirements; or

(C) 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:

(i) 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;

(ii) 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 NRC 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; and
- (6) Administering dosages of radioactive drugs to patients or human research subjects; and

(iii) Has obtained written attestation that the individual has satisfactorily completed the requirement in 180 NAC 7-043(C) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 180 NAC 7-041. The attestation must be obtained from either:

- (1) A preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-043, 7-047, or 7-051, or equivalent NRC or Agreement State requirements; or
- (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026, 7-043, 7-047, or 7-051, or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-043(C) of this section.

**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:

(A) Obtained from:

- (i) A manufacturer or preparer licensed according to 180 NAC 3-014.10 or equivalent NRC or Agreement State; or
- (ii) A PET radioactive drug producer licensed according to 180 NAC 3-010.11 or equivalent NRC or Agreement State; or

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

- (i) An authorized nuclear pharmacist;
- (ii) 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(A)(ii) (7); or
- (iii) An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in paragraph 180 NAC 7-044(B)(i) or the physician who is an authorized user in paragraph 180 NAC 7-044(B)(ii); or

(C) Obtained from and prepared by an NRC or Agreement State licensee for use in research according to a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or

(D) Prepared by the licensee for use in research according to a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the FDA.

#### **045. RADIONUCLIDE CONTAMINANTS.**

045.01 LIMITS. A licensee must not administer to humans a radioactive drug containing:

(A) More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15  $\mu$ Ci of molybdenum-99 per mCi of technetium-99m);

(B) More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02  $\mu$ Ci of strontium-82 per mCi of rubidium-82 chloride injection); or

(C) More than 0.02 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.02  $\mu$ Ci of strontium-85 per mCi of rubidium-82 chloride injection).

#### **045.02 CONCENTRATION MEASUREMENT IN RADIOACTIVE DRUG**

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

(A) Measure the concentration of radionuclide contaminant in each eluate after receipt of a molybdenum-99/technetium-99m generator; or

(B) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

045.03 STRONTIUM-82/RUBIDIUM-82 GENERATORS. 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.

045.04 RECORDS. A licensee who must measure radionuclide concentration must retain a record of each measurement according to 180 NAC 7-099.

045.05 REPORTING REQUIREMENT. A licensee must report according to 180 NAC 7-120 each occurrence of a concentration exceeding the limits specified in 180 NAC 7-045.01.

**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  $\mu$ Sv (0.1 mrem) per hour to 500  $\mu$ Sv (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  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The

instruments must be operable and calibrated according to 180 NAC 7-030.

**047. TRAINING FOR IMAGING AND LOCALIZATION STUDIES.** Other than 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:

047.01 CERTIFICATION. Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the NRC. The names of board certification that have been recognized by the Department, an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

- (A) 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(A)(i) through (A)(ii)(7); and
- (B) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

047.02 AUTHORIZED USER. Is an authorized user in 180 NAC 7-051 and meets the requirements in 180 NAC 7-047.03(A)(ii)(7) or equivalent NRC or Agreement State requirements; or

047.03 TRAINING AND EXPERIENCE. The physician has:

(A) 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:

(i) 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

(ii) 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(A)(ii)(7) or equivalent NRC or Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in 180 NAC 7-024 or 7-026 may provide the supervised work experience for 180 NAC 7-047.03(A)(ii)(7) of this section. 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; 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

(B) Obtained written attestation, that the individual has satisfactorily completed the requirements in 180 NAC 7-047.03(A) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 180 NAC 7-041 and 7-044. The attestation must be obtained from either:

- (i) A preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-047, or 7-051 and 7-047.03(A)(ii)(7), or equivalent NRC or Agreement State requirements; or
- (ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026, 7-047, or 7-051 and 7-047.03(A)(ii)(7), or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-47.03(A) of this section.

**048. USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED.** A licensee may use any unsealed radioactive material identified in 180 NAC 7-051 (B)(i)(2)(f) prepared for medical use and for which a written directive is required that is:

(A) Obtained from:

- (i) A manufacturer or preparer licensed in 180 NAC 3-014.10; or equivalent NRC or Agreement State; or

(ii) A PET radioactive drug producer licensed according to 180 NAC 3-010.11 or equivalent NRC or Agreement State; or

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

(i) 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;

(ii) An individual under the supervision of either as specified in 180 NAC 7-018; or

(iii) An individual under the supervision, as specified in 180 NAC 7-018, of the authorized nuclear pharmacist in 7-048(B)(i) or the physician who is authorized in 7-048(B)(ii); or

(C) Obtained from and prepared by the Department, NRC or Agreement State licensee according to a Radioactive Drug Research Committee's approval protocol or an Investigational New Drug protocol accepted by the FDA for use in research; or

(D) Prepared by the licensee for use in research according to an approved application or an Investigational New Drug protocol accepted by the FDA for use in research.

## **049. SAFETY INSTRUCTION AND SAFETY PRECAUTIONS.**

049.01 ADDITIONAL SAFETY REQUIREMENTS. In addition to the requirements of 180 NAC 10-003:

(A) A licensee must provide radiation safety instruction, initially and at least annually, to all personnel caring for patients or human research subjects who cannot be released according to 180 NAC 7-037. The instruction must be appropriate to the personnel's assigned duties and include:

(i) Patient or human research subject control;

(ii) Visitor control, to include:

(1) Routine visitation to hospitalized individuals according to 180 NAC 4-013.01(A); and

(2) Visitation authorized according to 180 NAC 4-013.03;

(iii) Contamination control;

(iv) Waste control; and

(v) Notification of the RSO or their designee and the authorized user if the patient or the human research subject has a medical emergency or dies; and

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

049.02 SAFETY PRECAUTIONS. Safety precautions must be followed as specified below.

(A) For each patient or human research subject who cannot be released under 180 NAC 7-037, a licensee must:

(i) 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 therapy with unsealed radioactive material and who also cannot be released under 180 NAC 7-037;

(ii) 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

(iii) Either:

- (1) Monitor material and items removed from the patient's or the human research subject's room to determine 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; and

(B) The RSO, or their designee, and the authorized user must be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee must also notify the Department according to 180 NAC 7-119 if it is possible any individual could receive exposures in excess of 180 NAC 4-013 as a result of the deceased's body; and

(C) 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 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.

**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  $\mu$ Sv (0.1 mrem) per hour to 1,000  $\mu$ Sv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments must be operable and calibrated according to 180 NAC 7-030.

**051. TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED.** Other than 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:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Department, an Agreement State, or the NRC who meets the requirements in 180 NAC 7-051(B)(i)(2)(f) and 7-051(B)(ii). Specialty Boards whose certification process has been recognized by an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website. To be recognized, a specialty board must require all candidates for certification to:

- (i) 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(B)(i)(1) through 7-051(B)(i)(2)(e). 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 Council on Postdoctoral Training of the American Osteopathic Association; and
- (ii) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(B) The physician has:

(i) 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:

(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, 7-051, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051(B), must also have experience in administering dosages in the same dosage category or categories, 180 NAC 7-051(B)(i)(2)(f), as the individual requesting authorized user status. The work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;  
(b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;  
(c) Calculating, measuring, and safely preparing patient or human research subject dosages;  
(d) Using administrative controls to prevent a misadministration 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 in each of the following categories. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under 180 NAC 7-085. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

- (i) 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;
- (ii) Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131. Experience with at least three cases in 180 NAC 7-051(B)(i)(2)(f)(ii) also satisfies the requirement in 180 NAC 7-051(B)(i)(2)(f)(i); and
- (iii) Parenteral administration of any radioactive drug that contains a radionuclide primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

(ii) Obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-051(B) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 180 NAC 7-048 for which the individual is requesting authorized user status. The attestation must be obtained from either:

- (1) A preceptor authorized user who meets the requirements in 180 NAC 7-026 or 7-051, or equivalent NRC or Agreement State requirements, and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or
- (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026 or 7-051, or equivalent NRC or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with

the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-051 (B).

**052. TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 IN QUANTITIES LESS THAN OR EQUAL TO 1.22 GIGABECQUERELS (33 MILLICURIES) FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED.**

Other than 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:

- (A) Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-052(C)(i) and (ii) and whose certification has been recognized by the Department, an Agreement State or the NRC. The names of board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website; or
- (B) Is an authorized user under 180 NAC 7-051(A), 7-051(B) for uses listed in 180 NAC 7-051(B)(i)(2)(f)(i) or (ii), 180 NAC 7-053, or equivalent NRC or Agreement State requirements; or
- (C) The physician has:

- (i) 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:

- (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;

- (ii) 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 NRC or Agreement State requirements. A supervising authorized user who meets the requirements in 180 NAC 7-051(B), must have experience in administering dosages as specified in 180 NAC 7-051(B)(i)(2)(f)(i) or (ii) 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 check 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 radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (6) 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

(iii) Obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-052(C)(i) and (ii) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 180 NAC 7-048. The attestation must be obtained from either:

- (1) A preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-052, 7-053, or equivalent NRC or Agreement State requirements, and has experience in administering dosages as specified in 180 NAC 7-051(B)(i)(2)(f)(i) or (i); or
- (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-052, 7-053, or equivalent NRC or Agreement State requirements, has experience in administering dosages as specified in 180 NAC 7-051(B)(i)(2)(f)(i) or (i), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-052(C).

**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.**

Other than 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:

- (A) Is certified by a medical specialty board whose certification process includes all of the requirements in 180 NAC 7-053(C)(i) and (ii) and whose certification has been recognized the Department, an Agreement State, or the NRC. The name of board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website; or
- (B) Is an authorized user under 180 NAC 7-051, for uses listed in 180 NAC 7-051 (B)(i)(2)(f)(ii), or equivalent Agreement State, or NRC requirements; or
- (C) The physician has:

(i) 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:

- (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;

(ii) Work experience, under the supervision of an authorized user who meets the requirements in 180 NAC 7-026, 7-051, 7-053, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in 180 NAC 7-051(B), must have experience in administering dosages as specified in 180 NAC 7-051(B)(i)(2)(f)(ii). 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 event involving the use of radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (6) 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

(iii) Obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 180 NAC 7-053(C)(i) and (ii), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 180 NAC 7-048. The attestation must be obtained from either:

- (1) A preceptor authorized user who meets the requirements in 7-026, 7-051, 7-053, equivalent NRC or Agreement State requirements, and has experience in administering dosages as specified in 7-051(B)(i)(2)(f)(ii); or
- (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 7-026, 7-051, 7-053, equivalent NRC or Agreement State requirements, has experience in administering dosages as specified in 7-051(B)(i)(2)(f)(ii), and concurs with the

attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7-053(C)(i) and (i).

#### **054. TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE.**

054.01 AUTHORIZED USER. Other than 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:

- (A) Is an authorized user under 180 NAC 7-051 for uses listed in 7-051(B)(i)(2)(f)(iii), or equivalent Agreement State or NRC requirements;
- (B) Is an authorized user under 180 NAC 7-063 or 7-084, or equivalent Agreement State or NRC requirements and who meets the requirements in 180 NAC 7-054.02; or
- (C) Is certified by a medical specialty board whose certification process has been recognized by the Department, the NRC or an Agreement State under 180 NAC 7-063 or 7-084; and who meets the requirements in 180 NAC 7-054.02.

054.02 TRAINING AND SUPERVISED WORK EXPERIENCE. The physician has:

- (A) Successfully completed eighty hours of classroom and laboratory training, applicable to parenteral administrations listed in 7-051(B)(i)(2)(f)(iii). The training must include:
  - (i) Radiation physics and instrumentation;
  - (ii) Radiation protection;
  - (iii) Mathematics pertaining to the use and measurement of radioactivity;
  - (iv) Chemistry of radioactive material for medical use; and
  - (v) Radiation biology;
- (B) 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 NRC or Agreement State requirements, in the parenteral administrations listed in 7-051(B)(i)(2)(f)(iii). A supervising authorized user who meets the requirements in 180 NAC 7-051, 7-054, or equivalent NRC or Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:
  - (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
  - (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in 180 NAC 7-051(B)(i)(2)(f)(iii); and

(C) Obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-054.02(A) and (B), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

- (i) A preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-051, or 7-054, or equivalent NRC or Agreement State requirements. A preceptor authorized user who meets the requirements in 180 NAC 7-051, or 7-054, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or
- (ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026, 7-051, or 7-054, or equivalent NRC or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-54.02 (A) and (B).

**055. USE OF SOURCES FOR MANUAL BRACHYTHERAPY.** A licensee must use only brachytherapy sources:

- (A) Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses not explicitly listed in the Sealed Source and Device Registry, but must be used according to the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
- (B) In research to deliver therapeutic doses for medical use according to an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of 180 NAC 7-021, (A) are met.

**056. SURVEYS AFTER SOURCE IMPLANT AND REMOVAL.** The licensee must:

- (A) Immediately after implanting sources in a patient or a human research subject, make a survey to locate and account for all sources that have not been implanted;
- (B) Immediately after removing the last temporary implant source from a patient or a human research subject, 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; and
- (C) Retain a record of the surveys according to 180 NAC 7-102.

**057. BRACHYTHERAPY SOURCES INVENTORY.** The licensee must:

- (A) Maintain accountability at all times for all brachytherapy sources in storage or use.
- (B) Promptly after removing sources from a patient or a human research subject, return brachytherapy sources to a secure storage area.
- (C) Maintain a record of the brachytherapy source accountability according to 180 NAC 7-103.

**058. SAFETY INSTRUCTION.** In addition to the requirements of 180 NAC 10-003, the licensee must:

(A) 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 cannot be released under 180 NAC 7-037. The instruction must be commensurate with the duties of the personnel and must include the following:

- (i) Size and appearance of the brachytherapy sources;
- (ii) Safe handling and shielding instructions;
- (iii) Patient or human research subject control;
- (iv) Visitor control, including both:

- (1) Routine visitation of hospitalized individual according to 180 NAC 4-013.01; and
- (2) Visitation authorized according to 180 NAC 4-013.01; and

(v) Notification of the RSO or their designee, and authorized user if the patient or the human research subject dies or has a medical emergency. The licensee must also notify the Department according to 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; and

(B) Retain a record of individuals receiving instruction required by 180 NAC 7-101.

**059. SAFETY PRECAUTIONS FOR PATIENTS OR HUMAN RESEARCH SUBJECTS RECEIVING BRACHYTHERAPY.**

**059.01 PATIENT OR HUMAN RESEARCH SUBJECT RECEIVING**

**BRACHYTHERAPY THAT CANNOT BE RELEASED.** For each patient or human research subject that is receiving brachytherapy that cannot be released according to 180 NAC 7-037 a licensee must:

- (A) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and
- (B) 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.

**059.02 RADIOLOGICAL EMERGENCY RESPONSE EQUIPMENT.** A licensee must have radiological emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

- (A) Dislodged from the patient; and
- (B) Lodged within the patient following removal of the source applicators.

**059.03 NOTIFICATION OF MEDICAL EMERGENCY OR DEATH.** The RSO, or their designee, and authorized user must be notified immediately if the hospitalized patient or human research subject has a medical emergency or dies.

**060. CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES.**

**060.01 USE PARAMETERS.** Before the first medical use of a brachytherapy source a licensee must:

- (A) Determine the source output or activity using a dosimetry system that meets the requirements of 180 NAC 7-072.01;
- (B) Determine source positioning accuracy within applicators; and
- (C) Use published protocols currently accepted by nationally recognized bodies to meet the requirements of 180 NAC 7-060.01(A) and (B).

**060.02 SOURCE MANUFACTURER OR CALIBRATION LABORATORY.** 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 according to 180 NAC 7-060.01.

**060.03 PHYSICAL DECAY CORRECTION.** 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.

**060.04 PERFORM OR REVIEW OF CALCULATION MEASUREMENTS.** An authorized medical physicist must perform or review the calculation measurements made according to 180 NAC 7-060.01, 7-060.02, or 7-060.03.

**060.05 STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS.**  
Requirements for licensees using strontium-90 sources for ophthalmic

treatments are as follows:

(A) Licensees who use strontium-90 for ophthalmic treatments must ensure certain activities specified in 180 NAC 7-060.05 (B) are performed by either:

- (i) An authorized medical physicist; or
- (ii) An individual who:

- (1) Is identified as an ophthalmic physicist on a specific medical use license issued by the Department, NRC, or an Agreement State; permit issued by a Department, NRC, or Agreement State broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by a NRC master material licensee broad scope medical use permittee;

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

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

- (4) Has documented training in:

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

- (b) Procedures for administrations requiring a written directive; and

- (5) Is performing the calibration measurements of brachytherapy sources as detailed in 180 NAC 7-060;

(B) The individuals identified in 180 NAC 060.05 (A) must:

- (i) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 180 NAC 7-060; and

- (ii) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is according to the written directive. These procedures must include the frequencies that the individual meeting the requirements in 180 NAC 7-060.05 (A) will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were according to the written directives; and

(C) Licensees must retain a record of the activity of each strontium-90 source according to 180 NAC 7-105.

060.06 RECORDS. A licensee must retain a record of each calibration according to 180 NAC 7-104.

**061. THERAPY-RELATED COMPUTER SYSTEMS.** The licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems according to published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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

**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  $\mu\text{Sv}$  (0.1 mrem) per hour to 1,000  $\mu\text{Sv}$  (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10  $\mu\text{Sv}$  (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments must be operable and calibrated according to 180 NAC 7-030.

**063. TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES.** Other than 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:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Department, an Agreement State or the NRC. The names of board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

- (i) 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 Council on Postdoctoral Training of the American Osteopathic Association; and
- (ii) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use manual brachytherapy; or

(B) The physician has:

- (i) Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

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

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

(2) 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 NRC or Agreement State requirements at a medical facility authorized to use radioactive materials under 180 NAC 7-055, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Checking survey meters for proper operation;
- (c) Preparing, implanting, and removing brachytherapy sources;
- (d) Maintaining running inventories of material on hand;
- (e) Using administrative controls to prevent a misadministration involving the use of radioactive material; and
- (f) Using emergency procedures to control radioactive material; and

(ii) 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 NRC 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 Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 180 NAC 7-063(B)(i)(2); and

(iii) Obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-063(B)(i) and (ii) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 180 NAC 7-055. The attestation must be obtained from either:

(1) A preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-063, or equivalent NRC or Agreement State requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026, 7-063, or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training

program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-063(B)(i) and (ii).

**064. TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90.** Other than 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) A physician who is an authorized user under 180 NAC 7-063 or equivalent NRC or Agreement State requirements; or

(B) A physician that has:

(i) Completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

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

(ii) 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:

- (1) Examination of each individual to be treated;
- (2) Calculation of the dose to be administered;
- (3) Administration of the dose; and
- (4) Follow up and review of each individual's case history; and

(iii) Obtained written attestation, signed by a preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-063, 7-064 or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in 180 NAC 7-064(B) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

## **065. USE OF SEALED SOURCES FOR DIAGNOSIS.**

**065.01 SEALED SOURCES NOT IN MEDICAL DEVICES.** A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used according to the radiation safety conditions and limitations described in the Sealed Source and Device

Registry.

065.02 MEDICAL DEVICES CONTAINING SEALED SOURCES. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used according to the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

065.03 SEALED SOURCES AND DEVICES USED IN RESEARCH. Sealed sources and devices for diagnostic medical uses may be used in research according to an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 180 NAC 7-021(A) are met.

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

(A) Is certified by a specialty board whose certification process includes all of the requirements in 180 NAC 7-066.03 and 7-066.04 whose certification has been recognized by an Agreement State or the NRC. The names of board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website; or  
(B) Is an authorized user for uses listed in 180 NAC 7-044, or equivalent NRC or Agreement State requirements; or  
(C) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology; and

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

**067. USE OF A SEALED SOURCE IN A REMOTE AFTERLOADER UNIT, TELETHERAPY UNIT, OR GAMMA STEREOTACTIC RADIOSURGERY UNIT.**

067.01 APPROVED SEALED SOURCE. A licensee must only use sealed sources:

- (A) As approved and as provided for in the NRC Sealed Source and Device Registry; or
- (B) In research according to an active Investigational Device Exemption application accepted by the FDA provided the requirements of 180 NAC 7-021(A) are met.

067.02 APPROVED DEVICES. A licensee must only use devices:

- (A) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used according to radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
- (B) In research according to an active Investigational Device Exemption application accepted by the FDA provided the requirements of 180 NAC 7-021(A) are met.

**068. SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS TREATED WITH A REMOTE AFTERLOADER UNIT.**

068.01 CONFIRMATION OF SOURCE REMOVAL. 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 or sources has been removed from the patient or human research subject and returned to the shielded position.

068.02 RECORDS. A licensee must retain a record of surveys according to 180 NAC 7-102.

**069. INSTALLATION, MAINTENANCE, ADJUSTMENT, AND REPAIR.**

069.01 CONFIRMATION OF SOURCE REMOVAL. Only a person specifically licensed by the NRC 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 or sources shielding, the source or sources driving unit, or other electronic or mechanical component that could expose the source or sources, reduce the shielding around the source or sources, or compromise the radiation safety of the unit or the source or sources.

069.02 LICENSE REQUIRED. Other than LDR remote afterloader units, only a person specifically licensed by the Department, the NRC 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.

069.03 LDR REMOTE AFTERLOADER UNIT. For a LDR remote afterloader unit, only a person specifically licensed by the Department, the NRC, an Agreement State or an authorized medical physicist may install, replace, relocate, or remove a sealed source or sources contained in the unit.

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

**070. SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

**070.01 SAFETY AND WRITTEN PROCEDURES.** A licensee must:

- (A) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
- (B) Permit only individuals approved by the authorized user, RSO, or authorized medical physicist to be present in the treatment room during treatment with the source or sources;
- (C) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
- (D) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source or sources in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:
  - (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
  - (ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
  - (iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

**070.02 PROCEDURE LOCATION.** A copy of the procedures required by 180 NAC 7-070.01(D) must be physically located at the unit console.

**070.03 INSTRUCTION POSTING.** A licensee must post instructions at the unit console to inform the operator of:

- (A) The location of the procedures required by 180 NAC 7-70.01(D); and
- (B) The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

**070.04 INSTRUCTION FREQUENCY.** A licensee must:

- (A) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training; and
- (B) Provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions must include:

- (i) The procedures identified in 180 NAC 7-070.01(D); and
- (ii) The operating procedures for the unit.

070.05 PARTICIPATION IN DRILLS AND EMERGENCY PROCEDURES. A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

070.06 RECORDS. A licensee must retain a record of individuals receiving instruction required by 180 NAC 7-070.04, according to 180 NAC 7-101.

## **071. SAFETY PRECAUTIONS FOR REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

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

071.02 ELECTRICAL INTERLOCK SYSTEM. A licensee must equip each entrance to the treatment room with an electrical interlock system that will:

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

071.03 AMBIENT RADIATION LEVELS. 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.

071.04 VIEWING AND INTERCOM SYSTEM. Other than low-dose remote afterloader units, a licensee must 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.

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

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

- (A) For LDR, MDR and PDR remote afterloader units, require:

- (i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has

been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

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

(B) For HDR remote afterloader units, require:

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

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

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

(D) Notify the RSO, or their 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.

**071.07 RADIOLOGICAL EMERGENCY RESPONSE EQUIPMENT.** A licensee must have applicable radiological emergency response equipment available near each treatment room to respond to a source that inadvertently:

(A) Remains in the unshielded position; or

(B) Lodges within the patient following completion of the treatment.

## **072. DOSIMETRY EQUIPMENT.**

**072.01 CALIBRATED DOSIMETRY SYSTEM.** Other than LDR 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.

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

(B) 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 the National Institute of Standards and Technology (NIST) or by a calibration laboratory accredited by the American Association of Physicists in Medicine (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.

072.02 SPOT-CHECK SYSTEM. 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 calibrated according to 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.

072.03 RECORDS. The licensee must retain a record of each calibration, intercomparison, and comparison according to 180 NAC 7-107.

### **073. FULL CALIBRATION MEASUREMENTS ON TELETHERAPY UNITS.**

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

- (A) Before the first medical use of the unit;
- (B) Before medical use under the following conditions:
  - (i) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
  - (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
  - (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- (C) At intervals not exceeding one year.

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

- (A) The output within plus or minus 3% for the range of field sizes and for the distance or range of distances used for medical use;
- (B) The coincidence of the radiation field and the field indicated by the light beam localizing device;

- (C) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- (D) Timer accuracy, and linearity over the range of use;
- (E) "On-off" error; and
- (F) The accuracy of all distance measuring and localization devices in medical use.

073.03 DOSIMETRY SYSTEM USAGE. 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(A) may then be made using a dosimetry system that indicates relative dose rates.

073.04 PROTOCOLS. A licensee must make full calibration measurements required by 180 NAC 7-073.01 according to published protocols accepted by nationally recognized bodies.

073.05 MATHEMATICAL CORRECTION OF OUTPUTS. A licensee must mathematically correct the outputs determined in 180 NAC 7-073.02, (A), 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.

073.06 CALIBRATION MEASUREMENT AND DECAY CORRECTIONS. 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 an authorized medical physicist.

073.07 RECORDS. A licensee must maintain a record of each calibration according to 180 NAC 7-108.

## **074. FULL CALIBRATION MEASUREMENTS ON REMOTE AFTERLOADER UNITS.**

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

- (A) Before the first medical use of the unit;
- (B) Before medical use under the following conditions:
  - (i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
  - (ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;
- (C) At intervals not exceeding one calendar quarter for HDR, MDR, and PDR remote afterloader units with sources whose half-life exceeds 75 days; and
- (D) At intervals not exceeding one year for LDR remote afterloader units.

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

- (A) The output within  $\pm 5\%$ ;
- (B) Source positioning accuracy to within  $\pm 1$  millimeter;
- (C) Source retraction with backup battery upon power failure;
- (D) Length of the source transfer tubes;
- (E) Timer accuracy and linearity over the typical range of use;
- (F) Length of the applicators; and
- (G) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

074.03 VERIFICATION OF INVENTORY AND SOURCE ARRANGEMENT. In addition to the requirements for full calibration for LDR remote afterloader units in 180 NAC 7-074.02, a licensee must perform an autoradiograph of the source or sources to verify inventory and source or sources arrangement at intervals not exceeding one calendar quarter.

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

074.05 PROTOCOLS. A licensee must make full calibration measurements required by 180 NAC 7-074.01 according to published protocols accepted by nationally recognized bodies.

074.06 SOURCE MANUFACTURER MEASUREMENTS. For LDR remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made according to 180 NAC 7-074.01 through 7-074.05.

074.07 ONE PERCENT PHYSICAL DECAY. A licensee must mathematically correct the outputs determined in 180 NAC 7-074.02(A) for physical decay at intervals consistent with one percent physical decay.

074.08 FULL CALIBRATION MEASUREMENTS AND PHYSICAL DECAY CORRECTIONS. 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.

074.09 RECORDS. A licensee must retain a record of each calibration according to 180 NAC 7-108.

## **075. FULL CALIBRATION MEASUREMENTS ON GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

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

- (A) Before the first medical use of the unit;
- (B) Before medical use under the following conditions:

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

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

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

- (A) The output within  $\pm 3\%$ ;
- (B) Relative helmet factors to verify that the helmet material provides the required shielding to the patient;
- (C) Isocenter coincidence to confirm the centering accuracy of the radiation beam relative to the alignment helmet openings;
- (D) Timer accuracy and linearity over the range of use;
- (E) On-off error;
- (F) Trunnion centricity to determine the rotational center of the source relative to the alignment helmet openings;
- (G) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
- (H) Helmet microswitches to determine if the switches terminate the radiation beam;
- (I) Emergency timing circuits; and
- (J) Stereotactic frames, localizing devices and trunnions.

075.03 DOSIMETRY SYSTEM. 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(A) may be made using a dosimetry system that indicates relative dose rates.

075.04 CALIBRATION MEASUREMENT PROTOCOLS. A licensee must make full calibration measurements required by 180 NAC 7-075.01 according to published protocols accepted by nationally recognized bodies.

075.05 MATHEMATICAL CORRECTION OF OUTPUTS. A licensee must mathematically correct the outputs determined in 180 NAC 7-075.02(A) at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

075.06 AUTHORIZED MEDICAL PHYSICIST. 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.

075.07 RECORDS. A licensee must retain a record of each calibration according to 180 NAC 7-108.

## **076. PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS.**

076.01 DETERMINANTS. 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:

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

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

076.03 RESULTS. 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.

076.04 SAFETY SPOT-CHECKS. 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:

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

076.05 SYSTEM MALFUNCTION. 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 other than as necessary to repair, replace, or check the malfunctioning system.

076.06 RECORDS. A licensee must retain a record of each spot-check required by 180 NAC 7-076.01 and 7-076.04 and according to 180 NAC 7-109.

## **077. PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS.**

077.01 SPOT-CHECK FREQUENCY. 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:

- (A) At the beginning of each day of use of a HDR, MDR, or PDR remote afterloader unit;
- (B) Prior to each patient treatment with a LDR remote afterloader unit; and
- (C) After each source installation.

077.02 WRITTEN PROCEDURES. 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.

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

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

- (A) Electrical interlocks at each remote afterloader unit room entrance;
- (B) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
- (C) Viewing and intercom systems in each HDR, MDR, and PDR remote afterloader facility;
- (D) Radiological emergency response equipment;
- (E) Radiation monitors used to indicate the source position;
- (F) Timer accuracy;
- (G) Clock, date and time, in the unit's computer; and
- (H) Decayed source or sources activity in the unit's computer.

077.05 SYSTEM MALFUNCTION. 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 other than as necessary to repair, replace, or check the malfunctioning system.

077.06 RECORDS. A licensee must retain a record of each check required by 180 NAC 7-077.04 according to 180 NAC 7-110.

**078. PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

078.01 FREQUENCY. 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:

- (A) Monthly;
- (B) Before the first use of the unit on a given day; and
- (C) After each source installation.

078.02 WRITTEN PROCEDURES. The licensee must have the authorized medical physicist:

- (A) Establish written procedures for performing the spot-checks required in 180 NAC 7-078.01; and
- (B) Review and sign the results of each spot-check required by 180 NAC 7-078.01 within fifteen 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 ten days in writing of the results of the spot check.

078.03 MINIMUM REQUIREMENTS. To satisfy the requirements of 180 NAC 7-078.01(A), spot-checks must, at a minimum:

- (A) Assure proper operation of:
  - (i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
  - (ii) Helmet microswitches;
  - (iii) Emergency timing circuits; and
  - (iv) Stereotactic frames, localizing devices, and trunnions; and
- (B) Determine:
  - (i) The output for one typical set of operating conditions measured with the dosimetry system described in 180 NAC 7-072.02;
  - (ii) The difference between the measurement made in 180 NAC 7-078.03(B)(i) and the anticipated output, expressed as a percentage of the anticipated output, or the value obtained at last full calibration corrected mathematically for physical decay;
  - (iii) Source output against computer calculation;
  - (iv) Timer accuracy and linearity over the range of use;
  - (v) On-off error; and
  - (vi) Trunnion centricity.

078.04 ASSURANCE OF PROPER OPERATION. To satisfy the requirements of 180 NAC 7-078.01(B) and (C), spot-checks must assure proper operation of:

- (A) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- (B) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
- (C) Viewing and intercom systems;
- (D) Timer termination;
- (E) Radiation monitors used to indicate room exposures; and
- (F) Emergency off buttons.

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

078.06 SYSTEM MALFUNCTION. 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 unless necessary to repair, replace, or check the malfunctioning system.

078.07 RECORDS. A licensee must retain a record of each check required by 180 NAC 7-078.03 and 7-078.04 and according to 180 NAC 7-111.

## **079. ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS.**

079.01 BEFORE MEDICAL USE. A licensee providing mobile remote afterloader service must:

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

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

- (A) Electrical interlocks on treatment area access points;
- (B) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
- (C) Viewing and intercom systems;
- (D) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
- (E) Radiation monitors used to indicate room exposures;
- (F) Source positioning accuracy; and
- (G) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

079.03 SIMULATED CYCLE OF TREATMENT. 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.

079.04 SYSTEM MALFUNCTION. 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 unless necessary to repair, replace, or check the malfunctioning system.

079.05 RECORDS. A licensee must retain a record of each check required by 180 NAC 7-079.02 according to 180 NAC 7-112.

## **080. RADIATION SURVEYS.**

080.01 RESULTS. 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.

080.02 SURVEY AFTER REPAIR. The licensee must perform the survey required by 180 NAC 7-080.01 upon installation of a new source and following repairs to the source or sources shielding, the source or sources driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source or sources, or compromise the radiation safety of the unit or the source or sources.

080.03 RECORDS. A licensee must retain a record of the radiation surveys required by 180 NAC 7-080.01 according to 180 NAC 7-113.

## **081. FULL-INSPECTION SERVICING FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

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

081.02 SPECIFICALLY LICENSED PERSONS. This inspection and servicing must only be performed by persons specifically licensed to do so by the Department, the NRC, or an Agreement State.

081.03 RECORDS. A licensee must maintain a record of the inspection and servicing according to 180 NAC 7-114.

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

- (A) The source-specific input parameters required by the dose calculation algorithm;
- (B) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (C) The accuracy of isodose plots and graphic displays;
- (D) The accuracy of the software used to determine radioactive source positions from radiographic images; and
- (E) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

**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  $\mu$ Sv (0.1 mrem) per hour to 1,000  $\mu$ Sv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments must be operable and calibrated according to 180 NAC 7-030.

**084. TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.** Other than 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:

- (A) Is certified by a medical specialty board whose certification process has been recognized by the Department, an Agreement State or the NRC and who meets the requirements of 180 NAC 7-084(C). The names of board certifications that have been recognized the Department, an Agreement State or the NRC are posted on the NRC's Medical Uses Licensee Toolkit website. To be recognized, a specialty board must require all candidates for certification to:
  - (i) 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 Council on Postdoctoral Training of the American Osteopathic Association; and
  - (ii) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or
- (B) The physician has:
  - (i) Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

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

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

(2) 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 NRC or Agreement State requirements at a medical facility that is authorized to use radioactive materials in 180 NAC 7-067, involving:

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

(ii) 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 NRC 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 Council 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(B)(i)(2); and

(iii) Obtained written attestation that the individual has satisfactorily completed the requirements in 180 NAC 7-084(B)(i) and (ii) and 7-087.03; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

- (1) A preceptor authorized user who meets the requirements in 180 NAC 7-026, 7-084, or equivalent NRC or Agreement State requirements, for the type or types of therapeutic medical unit for which the individual is requesting authorized user status; or
- (2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 180 NAC 7-026, 7-084, or equivalent NRC

or Agreement State requirements, for the type or types of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 180 NAC 7-084(B) (i) and (ii); and

(C) Has received training in device operation, safety procedures, and clinical use of the type or types 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 or types of use for which the individual is seeking authorization.

**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 provided that the applicant or licensee has:

(A) Submitted the information required by 180 NAC 7-008.02 through 7-008.04; and

(B) Received written approval from the NRC or Agreement State in a license and uses the material according to the regulations and specific conditions the NRC or Agreement State considers necessary for the medical use of the material.

**086. RECORDS OF AUTHORITY AND RESPONSIBILITIES FOR RADIATION PROTECTION PROGRAMS.** A licensee must:

(A) Retain a record of actions taken by the licensee's management according to 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.

(B) Retain a current copy of the authorities, duties and responsibilities of the RSO as required by 180 NAC 7-015.06, and a signed copy of the RSOs 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.

(C) For each ARSO appointed under 180 NAC 7-015.04 the licensee must retain, for 5 years after the ARSO is removed from the license, a copy of the written document appointing the ARSO signed by the licensee's management.

(D) Maintain minutes of each Radiation Safety Committee meeting held according to 180 NAC 7-015.09. Minutes must include:

- (i) The date of the meeting;
- (ii) Members present;

- (iii) Members absent; and
- (iv) Summary of deliberations and discussions.

**087. RECORDS OF RADIATION PROTECTION PROGRAM CHANGES.**

A licensee must retain a record of each radiation protection program made according to 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.

**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.

**089. RECORDS OF MISADMINISTRATION.** A licensee must retain a record of misadministration reported according to 180 NAC 7-115 for three years. The record must contain:

- (A) The licensee's name;
- (B) Name of the individual involved;
- (C) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the misadministration;
- (D) A brief description of the event;
- (E) Why it occurred;
- (F) The effect, if any, on the individual;
- (G) The actions if any taken, or planned, to prevent recurrence; and
- (H) 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.

**090. RECORDS OF A DOSE TO AN EMBRYO OR FETUS OR A NURSING CHILD.**

A licensee must retain a record of a dose to an embryo or fetus or a nursing child reported according to 180 NAC 7-117 for three years. The record must contain:

- (A) The licensee's name;
- (B) Name of all the individuals involved;
- (C) Identification number or if no other identification number is available, the social security number of the pregnant individual or nursing child who is the subject of the event;
- (D) A brief description of the event;
- (E) Why it occurred;
- (F) The effect, if any, on the embryo or fetus or nursing child;
- (G) The actions, if any, taken or planned, to prevent recurrence; and
- (H) 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.

**091. RECORDS OF CALIBRATION OF INSTRUMENTS USED TO MEASURE THE ACTIVITY 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:

- (A) The model and serial number of the instrument;
- (B) Calibration date;
- (C) Calibration results; and
- (D) Name of the individual who performed the calibration.

**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 items listed in 180 NAC 7-091 (A) through (D).

**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:

- (A) The radioactive drug;
- (B) Patient's or human research subject's name, or identification number if one has been assigned;
- (C) Prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);
- (D) Date and time of the dosage determination; and
- (E) Name of the individual who determined the dosage.

**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:

- (A) The model number of each source;
- (B) Serial number if one has been assigned;
- (C) Identity of each source radionuclide and its nominal activity;
- (D) Location of each source; and
- (E) Name of the individual who performed the test.

**095. RECORDS OF 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:

- (A) The survey date;
- (B) Survey results;
- (C) Specific survey instrument used; and
- (D) Name of the individual who performed the survey.

**096. RECORDS OF THE RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS CONTAINING RADIOACTIVE MATERIAL.** Each applicable record in this section must be maintained for three years after the date of the release of the individual. A licensee must retain a record:

- (A) Of the basis for authorizing the release of an individual according to 180 NAC 7-037, if the total effective dose equivalent is calculated by:

- (i) Using the retained activity rather than the activity administered;
- (ii) Using an occupancy factor less than 0.25 at 1 meter;
- (iii) Using the biological or effective half-life; or
- (iv) Considering the shielding by tissue; and

(B) That 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 1 mSv (0.1 rem).

**097. RECORDS OF ADMINISTRATIVE AND TECHNICAL REQUIREMENTS THAT APPLY TO THE PROVISION OF MOBILE SERVICES.** A licensee must retain:

- (A) A copy of each letter that permits the use of radioactive material at a client's address, as required by 180 NAC 7-009.02, for three years after the last provision of service; and
- (B) The record of each survey required by 180 NAC 7-038(F), 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.

**098. RECORDS OF DECAY-IN-STORAGE.** Records of decay-in-storage are to be retained as stated in 180 NAC 4-054.02.

**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:

- (A) 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);
- (B) Time and date of the measurement; and
- (C) Name of the individual who made the measurement.

**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.

**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) A list of topics covered;
- (B) The date of instruction;
- (C) Names of attendees; and
- (C) Names of individuals who provided the instruction.

## **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 items listed in 180 NAC 7-095 (A) through (D).

**103. RECORDS OF BRACHYTHERAPY SOURCE INVENTORY**. A licensee must maintain a record of brachytherapy source accountability required by 180 NAC 7-057 for three years. The record must include:

(A) For temporary implants:

- (i) 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
- (ii) 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; and

(B) For permanent implants:

- (i) 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;
- (ii) 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
- (iii) The number and activity of sources permanently implanted in the patient or human research subject.

## **104. RECORDS OF CALIBRATION MEASUREMENTS OF BRACHYTHERAPY**

**SOURCES**. 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:

- (A) The date of the calibration;
- (B) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
- (C) The source output or activity;
- (D) The source positioning accuracy within the applicators; and
- (E) The signature of the authorized medical physicist.

## **105. RECORDS OF DECAY OF STRONTIUM-90 SOURCES FOR**

**OPHTHALMIC TREATMENTS**. 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. The record must include:

- (A) The date and initial activity of the source as determined under 180 NAC 7-060; and
- (B) For each decay calculation, the date and the source activity as determined under 180 NAC 7-060.

**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:

- (A) The date;
- (B) Description of the service; and
- (C) Names of the individuals who performed the work.

**107. RECORDS OF DOSIMETRY EQUIPMENT.** A licensee must retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done according to 180 NAC 7-072 for the duration of the license. For each calibration, intercomparison, or comparison, the record must include:

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

**108. RECORDS OF TELETHERAPY, REMOTE AFTERLOADER, AND GAMMA STEREOTACTIC RADIOSURGERY FULL CALIBRATIONS.**

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. The record must include:

- (A) The date of the calibration;
- (B) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit or units, the source or sources, and the instruments used to calibrate the unit or units;
- (C) The results and an assessment of the full calibrations;
- (D) The results of the autoradiograph required for LDR remote afterloader units; and
- (E) The signature of the authorized medical physicist who performed the full calibration.

**109. RECORDS OF PERIODIC SPOT-CHECKS FOR TELETHERAPY UNITS.**

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

- (A) The date of the spot-check;
- (B) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

- (C) An assessment of timer linearity and constancy;
- (D) The calculated on-off error;
- (E) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
- (F) The determined accuracy of each distance measuring and localization device;
- (G) The difference between the anticipated output and the measured output;
- (H) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
- (I) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

#### **110. RECORDS OF PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER**

**UNITS.** A licensee must retain a record of each spot-check for remote afterloader units required by 180 NAC 7-077 for three years. The record must include, as applicable:

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

#### **111. RECORDS OF PERIODIC SPOT-CHECKS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

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

- (A) The date of the spot-check;
- (B) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
- (C) An assessment of timer linearity and accuracy;
- (D) The calculated on-off error;
- (E) A determination of trunnion centricity;
- (F) The difference between the anticipated output and the measured output;
- (G) An assessment of source output against computer calculations;
- (H) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices, trunnions; and
- (I) The name of the individual who performed the periodic spot-check and

the signature of the authorized medical physicist who reviewed the record of the spot-check.

**112. RECORDS OF ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS.**

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

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

**113. RECORDS OF SURVEYS OF THERAPEUTIC TREATMENT UNITS.**

A licensee must maintain a record of radiation surveys of treatment units made according to 180 NAC 7-080 for the duration of use of the unit. The record must include:

- (A) The date of the measurements;
- (B) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
- (C) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
- (D) The signature of the individual who performed the test.

**114. RECORDS OF FIVE YEAR INSPECTIONS FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.**

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. The record must contain:

- (A) The inspector's radioactive materials license number;
- (B) The inspection date;
- (C) The manufacturer's name and model number and serial number of both the treatment unit and source;
- (D) A list of components inspected and serviced, and the type of service; and
- (E) The signature of the inspector.

**115. REPORT AND NOTIFICATION OF MISADMINISTRATION.**

115.01 MISADMINISTRATION REPORTING. A licensee must report any event as a misadministration, other than events that result from patient intervention, where:

(A) The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage 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

- (1) The total dose delivered differs from the prescribed dose by twenty percent or more;
- (2) The total dosage delivered differs from the prescribed dosage by twenty percent or more or falls outside the prescribed dosage range; or
- (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty percent or more;

(ii) 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:

- (1) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;
- (2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
- (3) An administration of a dose or dosage to the wrong individual or human research subject;
- (4) An administration of a dose or dosage delivered by the wrong mode of treatment; or
- (5) A leaking sealed source; or

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

- (1) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given according to the written directive prepared or revised before administration; and
- (2) Fifty percent or more the expected dose to that site from the procedure if the administration had been given according to the written directive prepared or revised before administration.

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

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

- (ii) The total source strength administered outside of the treatment site exceeding twenty percent of the total source strength documented in the post-implantation portion of the written directive; or
- (iii) An administration that includes any of the following:

- (1) The wrong radionuclide;
- (2) The wrong individual or human research subject;
- (3) Sealed source or sources implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or
- (4) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

115.02 REPORTING. 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.

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

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

(A) The written report must include:

- (i) The licensee's name;
- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect, if any, on the individual or individuals who received the administration;
- (vi) What actions, if any, have been taken or are planned to prevent recurrence; and
- (vii) Certification that the licensee notified the individual, or the individual's responsible relative or guardian, and if not, why not; and

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

115.05 REFERRING PHYSICIAN NOTIFICATION. 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 they 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 misadministration, 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.

115.06 RIGHTS AND DUTIES. 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.

115.07 RECORDS. A licensee must retain a record of a misadministration according to 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.

**116. RECORDS OF SUPERVISION AUDITS.** A licensee must maintain a record of audits required by 180 NAC 7-018.01(D) 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.

**117. REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO OR FETUS OR A NURSING CHILD.**

117.01 DOSE TO EMBRYO OR FETUS. A licensee must report any dose to an embryo or 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 or fetus was specifically approved, in advance, by the authorized user.

117.02 DOSE TO A NURSING CHILD. 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:

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

117.03 TELEPHONE NOTIFICATION. The licensee must notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo or fetus or nursing child that requires a report in 180 NAC 7-117.01 or 7-117.02.

**117.04 WRITTEN REPORT REQUIREMENTS.** The licensee must submit a written report to the Department within 15 days after discovery of a dose to the embryo or fetus or nursing child that requires a report in 180 NAC 7-117.01 or 7-117.02.

(A) The written report must include:

- (i) The licensee's name;
- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect, if any, on the embryo or fetus or the nursing child;
- (vi) What actions, if any, have been taken or are planned to prevent recurrence; and
- (vii) Certification that the licensee notified the pregnant individual or mother, or the mother's or child's responsible relative or guardian, and if not, why not; and

(B) The report cannot contain the individual's or child's name or any other information that could lead to identification of the individual or child.

**117.05 NOTIFICATIONS.** 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 they 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 or 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 mothers 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 mothers 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.

**117.06 RECORDS.** A licensee must retain a record of a dose to an embryo or fetus or a nursing child according to 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.

**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  $\mu$ Ci) 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.

**119. NOTIFICATION OF DECEASED PATIENT OR HUMAN RESEARCH SUBJECTS CONTAINING RADIOACTIVE MATERIAL.** The licensee must:

(A) 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; and

(B) Submit a written report to the Department within 30 days after discovery that the patient or human research subject referenced in 180 NAC 7-119(A) has died. The written report must include:

- (i) The licensee's name;
- (ii) The date of death;
- (iii) The radionuclide, chemical and physical form, and calculated activity at time of death; and
- (iv) The names or titles and address or addresses of known individuals who might have received exposures exceeding 5 mSv (500 mrem).

**120. REPORT AND NOTIFICATION FOR AN ELUATE EXCEEDING PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATIONS.** The licensee must:

(A) Notify the Department and the distributor of the generator by telephone within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 180 NAC 7-045.01 at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number or lot number of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken; and

(B) Submit a written report to the Department within thirty calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 180 NAC 7-120(A).

