TITLE 180 CONTROL OF RADIATION

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Copies of the Code of Federal Regulations (CFR) cited in this Chapter are available for inspection at the Department of Health and Human Services Regulation and Licensure, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska.

21 CFR 800 through 1299 (April 1, 2002)

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TITLE 180 CONTROL OF RADIATION

CHAPTER 5 RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

5-001 SCOPE AND AUTHORITY

5-001.01 180 NAC 5 prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 3519.

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5-001.02 The provisions and requirements of 180 NAC 5 are in addition to, and not in substitution for, other requirements of Title 180. In particular, the general requirements and provisions of 180 NAC 1, 2, 3, 4, 10, 13, 17 and 18 apply to applicants, licensees and registrants subject to 180 NAC 5. 180 NAC 3 and 13 apply to licensing and transportation of radioactive material and 180 NAC 2 applies to registration of radiation machines. Except for chapters which are applicable only to sealed radioactive source, radiation machines and sealed radioactive sources are both covered by 180 NAC 5. 180 NAC 5 does not apply to medical uses of sources of radiation which are addressed in 180 NAC 6, 7 and 9.

5-001.03 21 CFR as published on April 1, 2002 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

5-001.04 National Bureau of Standards Handbook 136 issued 1-1981 as referred to in this Chapter is herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509

5-002 DEFINITIONS: As used in 180 NAC 5, the following definitions apply:

Annual refresher safety training means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review must

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include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review must also provide opportunities for employees to ask safety questions.

ANSI means the American National Standards Institute.

Associated equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source.[1]

Cabinet radiography means industrial radiography conducted in an enclosure or cabinet so shielded that radiation levels at every location on the exterior meet the limitations specified in 180 NAC 4-013.01, 4-013.02, and 4-013.03.

Cabinet x-ray system means a x-ray system with the x-ray tube installed in an enclosure that is independent of existing architectural structures except the floor. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. A x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

Camera see Radiographic exposure device.

Certifiable cabinet x-ray system means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

Certified cabinet x-ray system means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

Certifying entity means an independent certifying organization meeting the requirements in Appendix A of 180 NAC 5 or a state regulatory program meeting the requirements in Appendix A, Parts II and III of 180 NAC 5.

Collimator means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control cable (Drive cable) means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

Control drive mechanism means a device that enables the source assembly to be moved into and out of the exposure device.

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[1] e.g., guide tube, control tube, control (drive) cable, removable stop, "J" tube and collimator when used as an exposure head.

Control tube means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

Drive cable see Control cable.

Exposure head means a device that locates the gamma radiography sealed source in the selected working position.[2]

Field station means a facility where sources of radiation may be stored or used and from which equipment is dispatched.

Guide tube (Projection sheath) means a flexible or rigid tube or "J" tube for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Hands-on experience means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2000 hours of hands-on experience required for an Radiation Safety Officer in 180 NAC 5-015.01, item 2, or the hands-on experience for a radiographer as required by 180 NAC 5-016.01. Deleted: .

Independent certifying organization means an independent organization that meets all of the criteria of Appendix A to 180 NAC 5.

Industrial radiography (Radiography) means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

Permanent radiographic installation means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

Pigtail see Source assembly.

Pill see Sealed source.

Practical examination means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

Projection sheath see Guide tube.

[2]An exposure head is also known as a source stop.

Projector see Radiographic exposure device.

Radiation Safety Officer for "industrial radiography" means an individual with the responsibility for the overall radiation safety protection program on behalf of the licensee or registrant and who meets the requirements of 180 NAC 5-015.

Radiographer means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency's regulations and the conditions of the license or registration.

Radiographer's assistant means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

Radiographer certification means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 180 NAC 15-016.

Radiographic exposure device (Camera, Projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic operations means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting (except by common or contract carriers), or storing a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

Radiography see Industrial radiography.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

Sealed source see 180 NAC 1-002.

Shielded position means the location within the radiographic exposure device, source changer or storage container that, by manufacturer's design, is the proper location for storage of the sealed source.

Source assembly (Pigtail) means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

Source changer means a device designed and used for replacement of sealed sources in radiographic exposure devices. They may also be used for transporting and storing sealed source.

Storage area means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, sealed source, or a storage container, when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

Storage container means a device in which sealed sources or radiation machines are secured or stored.

Temporary job site means a location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) of use authorized on the license or registration.

Underwater radiography means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

5-003 EXEMPTIONS

5-003.01 Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of 180 NAC 5 except for the following:

1. For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

   a. No registrant may permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with 180 NAC 5-003.01, item 1, must be maintained for Agency inspection until disposal is authorized by the Agency.

   b. Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests must be maintained for Agency inspection until disposal is authorized by the Agency.

   c. The registrant must perform an evaluation of the radiation dose limits to determine compliance with 180 NAC 4-013.01, 4-013.02, and 4-013.03, and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not to exceed one year. Records of these evaluations must be maintained for Agency inspection for two years after the evaluation.

5-003.02 Industrial uses of hand-held light intensified imaging devices are exempt from the rules in 180 NAC 5 if the dose rate 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour. Devices which exceed this limit must meet the applicable requirements of 180 NAC 5 and the licensing or registration requirements of 180 NAC 2 or 180 NAC 3, as applicable.

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5-004 LICENSING AND REGISTRATION REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS

5-004.01 The Agency will approve an application for specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements and pays applicable fees specified in 180 NAC 18:

1. The applicant satisfies the general requirements specified in 180 NAC 2 for radiation machine facilities or 180 NAC 3 for radioactive material, as applicable, and any special requirements contained in 180 NAC 5;
2. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of 180 NAC 5-016:

3. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;
4. The applicant submits written operating and emergency procedures as described in 180 NAC 5-017;
5. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in 180 NAC 5-016.05;
6. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;
7. The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 180 NAC 5-015.01;
8. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test and the qualifications of the persons(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

    a. Methods of collecting the samples;
    b. Qualifications of the individual who analyzes the samples;
    c. Instruments to be used; and
    d. Methods of analyzing the samples

9. If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 180 NAC 5-008 and 180 NAC 5-019.07, item 4.
10. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.
11. The applicant identifies the location(s) where all records required by this and other Chapters of Title 180 will be maintained.
12. If an application includes underwater radiography, a description of:

Deleted: a. . For 2 years after May 27, 2000, the applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in 180 NAC 5-016.07.¶
b. . After 2 years from May 27, 2000 , the applicant need not describe the initial training and examination program for radiographers in the subjects outlined in 180 NAC 5-016.07.

a. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
b. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
c. Methods for gas-tight encapsulation of equipment.

5-005 PERFORMANCE REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY EQUIPMENT: Equipment used in industrial radiographic operations must meet the following minimum criteria:

5-005.01 Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication has been incorporated herein by reference and is available for viewing at the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509-5007.

5-005.02 In addition to the requirements specified in 180 NAC 5-005.01, the following requirements apply to radiographic exposure devices, source chargers, source assemblies and sealed sources;

1. The licensee must ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

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   a. Chemical symbol and mass number of the radionuclide in the device;
   b. Activity and the date on which this activity was last measured;
   c. Model or product code and serial number of the sealed source;
   d. Name of the manufacturer of the sealed source; and
   e. Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of 180 NAC 13.
3. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Agency or other approval body.

5-005.03 In addition to the requirements specified in 180 NAC 5-005.01 and 5-005.02, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.
3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
4. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER -- RADIOACTIVE"

The label may not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.
6. Guide tubes must be used when moving the source out of the device.
7. An exposure head or similar device designed to prevent the source of assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during the industrial radiography operations.
8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.
9. Source changes must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

5-005.04 All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of 180 NAC 5; and

5-005.05 As an exception to 180 NAC 5-005.01, equipment used in industrial radiographic operations need not comply with Section 8.9.2 (c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

5-006 LIMITS ON EXTERNAL RADIATION LEVELS FROM STORAGE CONTAINERS AND SOURCE CHANGERS: The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

5-007 LOCKING OF SOURCES OF RADIATION, STORAGE CONTAINERS AND SOURCE CHANGERS

5-007.01 Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be locked when not under

the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 180 NAC 5-021[3]. In addition, during radiographic operations the sealed source assembly must be secured in a shielded position each time the source is returned to that position.

5-007.02 Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.[4]

5-007.03 The control panel of each radiation machine must be equipped with a lock that will prevent the unauthorized use of a x-ray system or the accidental production of radiation. The radiation machine must be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

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5-008 RADIATION SURVEY INSTRUMENTS

5-008.01 The licensee or registrant must keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by 180 NAC 4 and 180 NAC 5 . Instrumentation required by 180 NAC 5 must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

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5-008.02 The licensee or registrant must have each radiation survey instrument required under 180 NAC 5-008.01 calibrated:

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1. At energies appropriate for use and at intervals not to exceed 6 months or after instrument servicing, except for battery changes;
2. 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 of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and
3. So that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.

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5-008.03 The licensee or registrant must maintain records of the results of the instrument calibrations in accordance with 180 NAC 5-025.

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5-009 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES

5-009.01 The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons

[3]If a keyed lock, the key must be removed at all times.

[4]If a keyed lock, the key must be removed at all times.

authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State.

5-009.02 The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State.

5-009.03 Testing and recordkeeping requirements.

1. Each licensee who uses a sealed source must have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the sources must be performed using a method approved by the Agency, the U.S. Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 μCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Deleted: shall
2. The licensee must maintain records of the leak tests in accordance with 180 NAC 5-026. Deleted: shall
3. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

5-009.04 Any test conducted pursuant to 180 NAC 5-009.02 and 180 NAC 5-009.03 that reveals the presence of 185 becquerel (0.005 μCi) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee must immediately withdraw the equipment involved from use and must have it decontaminated and repaired or disposed of in accordance with Agency regulations. A report must be filed with the Agency within 5 days of any test with results that exceed the threshold in 180 NAC 5, describing the equipment involved, the test results, and the corrective action taken. Deleted: shall Deleted: shall

5-009.05 Each exposure device using depleted uranium (DU) shielding and an S-tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerel (0.005μCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform the analysis. Should such testing reveal the presence of 185 becquerel (0.005μCi) or more of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with 180 NAC 5-026.

5-010 QUARTERLY INVENTORY

5-010.01 Each licensee or registrant must conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license. Deleted: shall

5-010.02 The licensee or registrant must maintain records of the quarterly inventory in accordance with 180 NAC 5-027. Deleted: shall

5-011 INSPECTION AND MAINTENANCE OF RADIATION MACHINES, RADIOGRAPHIC EXPOSURE DEVICES, TRANSPORT, AND STORAGE CONTAINERS, ASSOCIATED EQUIPMENT, SOURCE CHANGERS, AND SURVEY INSTRUMENTS

5-011.01 The licensee or registrant must perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that: Deleted: shall

1. The equipment is in good working condition;
2. The sources are adequately shielded; and
3. Required labeling is present.

5-011.02 Survey instrument operability must be performed using check sources or other appropriate means.

5-011.03 If equipment problems are found, the equipment must be removed from service until repaired.

5-011.04 Each licensee or registrant must have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired. Deleted: shall

5-011.05 The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

5-011.06 Records of equipment problems and of any maintenance performed under 180 NAC 5-011 must be made in accordance with 180 NAC 5-029.

5-011.07 A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 180 NAC 5-011 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirement, is deemed to satisfy the requirements of 180 NAC 13-007 and 180 NAC 13-021.

5-012 PERMANENT RADIOGRAPHIC INSTALLATIONS

5-012.01 Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

1. An entrance control of the type described in 180 NAC 4-023.01, item 1, that causes the radiation level upon entry into the area to be reduced; or

2. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible sign must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

5-012.02 The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in 180 NAC 5-012.01, item 1, must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of 180 NAC 5-021 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 180 NAC 5-030.

5-013 LABELING, STORAGE, AND TRANSPORTATION

5-013.01 The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION*
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")
* or "DANGER"

5-013.02 The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 180 NAC 13.

5-013.03 Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee must store radioactive material in a manner that will minimize danger from explosion or fire.

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5-013.04 The licensee must lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal. Deleted: shall

5-013.05 The licensee's or registrant's name and city or town where the main business office is located must be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use. Deleted: shall

RADIATION SAFETY REQUIREMENTS

5-014 CONDUCTING INDUSTRIAL RADIOGRAPHIC OPERATIONS

5-014.01 Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 180 NAC 5-016.03. The additional qualified individual must observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present. Deleted: shall

5-014.02 All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

5-014.03 Except when physically impossible, collimators must be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device. Deleted: shall

5-014.04 A licensee or registrant may conduct underwater radiography only if procedures have been approved by the Agency, the U.S. Nuclear Regulatory Commission, or by another Agreement State.

5-015 RADIATION SAFETY OFFICER: The Radiation Safety Officer must ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program. Deleted: shall

5-015.01 The minimum qualifications, training, and experience for Radiation Safety Officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of 180 NAC 5-016.01
2. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and
3. Formal training in the establishment and maintenance of a radiation safety protection program.

5-015.02 The Agency will consider alternatives when the Radiation Safety Officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

5-015.03 The specific duties and authorities of the Radiation Safety Officer include:

1. Establishing and overseeing all operating, emergency, and ALARA procedures as required by 180 NAC 4 and reviewing them regularly to ensure that they conform to Agency regulations and the license or registration conditions;
2. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;
3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;
4. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by 180 NAC 4; and
5. Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

5-016 TRAINING

5-016.01 The licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received at least 40 hours of training in the subjects outlined in 5-016.07, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of 180 NAC 5. The on the job training must include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours).

5-016.02 In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received copies and instruction in the requirements described in the regulations contained in 180 NAC 5, and applicable chapters of 180 NAC 4, 10, and 13, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;
2. Has demonstrated an understanding of items in 180 NAC 5-016.02, item 1, by successful completion of a written or oral examination;
3. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and
4. Has demonstrated understanding of the use of the equipment described in 180 NAC 5-016.02, item 3, by successful completion of a practical examination.

Deleted: 5-015.04 Licensees and registrants will have 2 years from May 27, 2000 to meet the requirements of 180 NAC 5-015.01 and 5-015.02.

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5-016.03 The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in 180 NAC 5, and applicable 180 NAC 4, 10, and 13, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;
2. Has demonstrated an understanding of items 180 NAC 5-016.03, item 1, by successful completion of a written or oral examination;
3. Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and
4. Has demonstrated understanding of the use of the equipment described in 180 NAC 5-016.03, item 3, by successful completion of a practical examination.

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5-016.04 The licensee or registrant must provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

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5-016.05 Except as provided in 180 NAC 5-016.05, item 4, the Radiation Safety Officer or designee must conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's regulations, license or registration requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

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1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and
2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 180 NAC 5-016.02, item 3, and the radiographer's assistant must demonstrate knowledge of the training requirement of 180 NAC 5-016.03, item 3, by a practical examination before these individuals can next participate in a radiographic operation.
3. The Agency may consider alternatives in those situations where the individual serves as both radiographer and Radiation Safety Officer.
4. In those operations where a single individual serves as both radiographer and Radiation Safety Officer, and performs all radiography operations, an inspection program is not required.

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5-016.06 The licensee or registrant must maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 180 NAC 5-031.

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5-016.07 The licensee or registrant must include the following subjects required in 180 NAC 5-016.01:

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1. Fundamentals of radiation safety including:

   a. Characteristics of gamma and x-radiation;
   b. Units of radiation dose and quantity of radioactivity;
   c. Hazards of exposure to radiation;
   d. Levels of radiation from sources of radiation; and
   e. Methods of controlling radiation dose (time, distance, and shielding);

2. Radiation detection instruments including:

   a. Use, operation, calibration, and limitations of radiation survey instruments;
   b. Survey techniques; and
   c. Use of personnel monitoring equipment;

3. Equipment to be used including:

   a. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);
   b. Operation and control of radiation machines;
   c. Storage, control, and disposal of sources of radiation; and
   d. Inspection and maintenance of equipment.

4. The requirements of pertinent state and federal regulations; and
5. Case histories of accidents in radiography.

5-016.08 Records of radiographer certification maintained in accordance with 180 NAC 5-031.01 provide appropriate affirmation of certification requirements specified in180 NAC 005-016.01, item 1.

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5-016.08 Licensees or registrants will have until 1 year May 27, 2000 to comply with the additional training requirements specified in 180 NAC 5-016.02, item 1. and 180 NAC 5-016.03, item 1.¶
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5-017 OPERATING AND EMERGENCY PROCEDURES

5-017.01 Operating and emergency procedures must include, as a minimum, instructions in the following:

1. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in 180 NAC 4.;
2. Methods and occasions for conducting radiation surveys;
3. Methods of posting and controlling access to radiographic areas;
4. Methods and occasions for locking and securing sources of radiation;
5. Personnel monitoring and the use of personnel monitoring equipment;
6. Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the equipment during transportation as described in 180 NAC 13;
7. The inspection, maintenance, and operability checks of radiographic exposure , devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;

8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;
9. The procedure(s) for identifying and reporting defects and noncompliance, as required by 180 NAC 5-037;
10. The procedure for notifying proper persons in the event of an accident or incident;
11. Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;
12. Source recovery procedure if licensee will perform source recoveries; and
13. Maintenance of records.

5-017.02 The licensee or registrant must maintain copies of current operating and emergency procedures in accordance with 180 NAC 5-032 and180 NAC 5-036.

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5-018 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

5-018.01 The radiographer's assistant must be under the personal supervision of a radiographer when using sources of radiation or conducting radiation surveys required by 180 NAC 5-020.02 to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

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1. The radiographer's physical presence at the site where the sources of radiation are being used;
2. The availability of the radiographer to give immediate assistance if required; and
3. The radiographer's direct observation of the assistant's performance of the operations referred to in 180 NAC 5-018.01.

5-019 PERSONNEL MONITORING

5-019.01 The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarming ratemeter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the use of an alarming ratemeter is not required.

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Deleted: returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge, TLD or OSLD in 14 calendar days, such circumstances must be documented and available for review by the Agency.

1. Pocket dosimeters must have a range from zero to two millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.
2. Each personnel dosimeter must be assigned to and worn by only one individual;
3. Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months.
4. After replacement, each personnel dosimeter must be processed as soon as possible.

5-019.02 Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with180 NAC 5-033.

5-019.03 Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 180 NAC 5-033. Acceptable dosimeters must read within plus or minus 20% of the true radiation exposure.

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5-019.04 If an individual's pocket dosimeter is found to be off-scale, or if his/her electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the Radiation Safety Officer or the Radiation Safety Officer's designee. The results of this determination must be included in the records maintained in accordance with180 NAC 5-033.

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5-019.05 If the personnel dosimeter that is required by 180 NAC 5-019 is lost or damaged, the worker must cease work immediately until a replacement personnel dosimeter meeting the requirements of 180 NAC 5-019 is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with 180 NAC 5-033.

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5-019.06 Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with 180 NAC 5-033.

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5-019.07 Each alarming ratemeter must:

1. Be checked to ensure that the alarm functions properly before using at the start of each shift;
2. Be set to give an alarm signal at a preset dose rate of 5 millisieverts per hour (500 mrem/hr); with an accuracy of plus or minus 20% of the true radiation dose rate;
3. Require special means to change the preset alarm function; and
4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee must maintain records of alarming ratemeter calibrations in accordance with 180 NAC 5-033.

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5-020 RADIATION SURVEYS: The licensee or registrant must:

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5-020.01 Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 180 NAC 5-008;

5-020.02 Conduct a survey of the radiographic exposure device and guide tube after each exposure when approaching the device or the guide tube. The survey must determine that a sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines must be surveyed after each exposure to determine that the machine is off;

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5-020.03 Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure devices is placed in a storage area as defined in 180 NAC 5-002, to ensure that the sealed source is in its shielded position; and

5-020.04 Maintain records in accordance with 180 NAC 5-034.

5-021 SURVEILLANCE: During each radiographic operation, the radiographer must ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in 180 NAC 1 except as permanent radiographic installations where all entryways are locked and the requirements of 180 NAC 5-012 are met. Deleted: shall

5-022 POSTING: All areas in which industrial radiography is being performed must be conspicuously posted as required by 180 NAC 4-034. The exceptions listed in 80 NAC 4-035 do not apply to industrial radiographic operations. Deleted: 3

RECORDKEEPING REQUIREMENTS

5-023 RECORDS FOR INDUSTRIAL RADIOGRAPHY: Each licensee or registrant must maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration. Deleted: shall

5-024 RECORDS OF RECEIPT AND TRANSFER OF SOURCES OF RADIATION

5-024.01 Each licensee or registrant must maintain records showing the receipts and transfers of sealed sources, devices for using DU for shielding, and radiation machines, and retain each record for 3 years after it is made. Deleted: shall

5-024.02 These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

5-025 RECORDS OF RADIATION SURVEY INSTRUMENT: Each licensee or registrant must maintain records of the calibrations of its radiation survey instruments that are required under 180 NAC 5-008 and retain each record for 3 years after it is made. Deleted: shall

5-026 RECORDS OF LEAK TESTING OF SEALED SOURCES AND DEVICES CONTAINING DU: Each licensee must maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (μCi). The licensee must retain each record for 3 years after it is made or until the source in storage is removed. Deleted: shall Deleted: shall

5-027 RECORDS OF QUARTERLY INVENTORY

5-027.01 Each licensee or registrant must maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 180 NAC 5-010, and retain each record for 3 years from the date of inventory. Deleted: shall

5-027.02 The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

5-028 UTILIZATION LOGS

5-028.01 Each licensee or registrant must maintain utilization logs showing for each source of radiation the following information: Deleted: shall

1. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;
2. The identity and signature of the radiographer to whom assigned;
3. The location and dates of use, including the dates removed and returned to storage; and
4. For permanent radiographic installations, the dates each radiation machine is energized.

5-028.02 The licensee or registrant must retain the logs required by 180 NAC 5-028.01 for 3 years after the log is made. Deleted: shall

5-029 RECORDS OF INSPECTION AND MAINTENANCE OF RADIATION MACHINES, RADIOGRAPHIC EXPOSURE DEVICES, TRANSPORT, AND STORAGE CONTAINERS, ASSOCIATED EQUIPMENT, SOURCE CHANGERS, AND SURVEY INSTRUMENTS

5-029.01 Each licensee or registrant must maintain records specified in 180 NAC 5-011 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made. Deleted: shall

5-029.02 The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

5-030 RECORDS OF ALARM SYSTEM AND ENTRANCE CONTROL CHECKS AT PERMANENT RADIOGRAPHIC INSTALLATIONS: Each licensee or registrant must maintain records of alarm systems and entrance control device tests required by 180 NAC 5-012 and retain each record for 3 years after the record is made. Deleted: shall

5-031 RECORDS OF TRAINING AND CERTIFICATION

5-031.01 Each licensee or registrant must maintain the following records for 3 years: Deleted: shall

1. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, names of individuals conducting and receiving the oral and

practical examinations, and a list of items tested and the results of the oral and practical examinations; and

2. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the Radiation Safety Officer or designee.

5-032. COPIES OF OPERATING AND EMERGENCY PROCEDURES: Each licensee or registrant must maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for 3 years after the changes is made.

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5-033 RECORDS OF PERSONNEL MONITORING

5-033.01 Each licensee or registrant must maintain the following exposure records specified in 180 NAC 5-019:

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1. Direct reading dosimeter readings and yearly operability checks required by 180 NAC 5-019.02 and 5-019.03 for 3 years after the record is made;
2. Records of alarming ratemeter calibrations 3 years after the record is made;
3. Personnel dosimeter results received from the accredited NVLAP processor until the Agency terminates the license or registration; and

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4. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost of damaged personnel dosimeters until the Agency terminates the license or registration.

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5-034 RECORDS OF RADIATION SURVEYS: Each licensee must maintain a record of each exposure device survey conducted before the device is placed in storage as specified in 180 NAC 5-020.03. Each record must be maintained for 3 years after the record is made.

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5-035 FORM OF RECORDS: Each record required by 180 NAC 5 must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials and signatures. The licensee or registrant must maintain adequate safeguards against tampering with and the loss of records.

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5-036 LOCATION OF DOCUMENTS AND RECORDS

5-036.01 Each licensee or registrant must maintain copies of records required by 180 NAC 5 and other applicable chapters of Title 180 at the location specified in 180 NAC 5-004.01, item 11.

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5-036.02 Each licensee or registrant must also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite; Deleted: shall

1. The license or registration authorizing the use of sources of radiation;
2. A copy of 180 NAC 1, 4, 5, and 10 ;
3. Utilization logs for each source of radiation dispatched from the location as required by 180 NAC 5-028;
4. Records of equipment problems identified in daily checks of equipment as required by 180 NAC 5-029.01;
5. Records of alarm system and entrance control checks required by 180 NAC 5-030, if applicable;
6. Records of dosimeter readings as required by 180 NAC 5-033;
7. Operating and emergency procedures required by 180 NAC 5-032;
8. Evidence of the latest calibrations and of radiation survey instruments in use at the site, as required by 180 NAC 5-025;
9. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 180 NAC 5-033
10. Survey records as required by 180 NAC 5-034 and 180 NAC 4-049 as applicable, for the period of operation at that site; Deleted: 7
11. The shipping papers for the transportation of radioactive materials required by 180 NAC 013 and;
12. When operating under reciprocity pursuant to 180 NAC 3 or registration pursuant to 180 NAC 2, a copy of the applicable State license or registration, or U.S. Nuclear Regulatory Commission license authorizing the use of sources of radiation.

NOTIFICATIONS

5-037 NOTIFICATIONS

5-037.01 In addition to the reporting requirements specified in 180 NAC 3-026 and 180 NAC 4, each licensee or registrant must provide a written report to the Agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment: Deleted: shall

1. Unintentional disconnection of the source assembly from the control cable;
2. Inability to retract the source assembly to its fully shielded position and secure it in this position;
3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or
4. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

5-037.02 The licensee or registrant must include the following information in each report submitted under 180 NAC 5-037.01, and in each report of overexposure submitted under 180 NAC 4-060 which involves failure of safety components of radiography equipment: Deleted: shall Deleted: 58

1. Description of the equipment problem;
2. Cause of each incident, if known;

3. Name of the manufacturer and model number of equipment involved in the incident;
4. Place, date, and time of the incident;
5. Actions taken to establish normal operations;
6. Corrective actions taken or planned to prevent recurrence; and
7. Names and qualifications of personnel involved in the incident.

5-037.03 Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, must notify the Agency prior to exceeding the 180 days. Deleted: shall

5-038 RECIPROCITY

5-038.01 All reciprocal recognition of licenses by the Agency will be granted in accordance with 180 NAC 3-028.

5-038.02 Reciprocal recognition by the Agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 180 NAC 5-002;
2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 180 NAC 5-016.01;
3. The applicant presents the certification to the Agency prior to the entry into the state; and
4. No escalated enforcement action is pending with the U.S. Nuclear Regulatory Commission or in any other State.

5-038.03 Certified individuals who are granted reciprocity by the Agency must maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, must met the requirements of 180 NAC 5-016.01. Deleted: shall Deleted: shall

5-039 SPECIFIC REQUIREMENTS FOR RADIOGRAPHIC PERSONNEL PERFORMING INDUSTRIAL RADIOGRAPHY

5-039.01 At a job site, the following must be supplied by the licensee or registrant: Deleted: shall

1. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;
2. A current whole body personnel monitor (film badge, TLD or OSLD) for each person performing radiographic operations;
3. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations;
4. An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and
5. The appropriate barrier ropes and signs.

5-039.02 Each radiographer at a job site must have on his/her person a valid certification ID card issued by a certifying entity.

5-039.03 Industrial radiographic operations must not be performed if any of the items in 180 NAC 5-039.01 and 5-039.02 are not available at the job site or are inoperable.

5-039.04 During an inspection, the Agency may terminate an operation if any of the items in 180 NAC 5-039.01 and 180 NAC 5-039.02 are not available or operable, or if the required number of radiographic personnel are not present. Operations must not be resumed until all required conditions are met.

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APPENDIX A

I. Requirements for an Independent Certifying Organization

An independent certifying organization must: Deleted: shall

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

2. Make its membership available to the general public nationwide. Membership must not be restricted because of race, color, religion, sex, age, national origin or disability; Deleted: shall

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its field of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the U.S. Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Agency of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs

All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in 180 NAC 5-016.07 or equivalent State or U.S. Nuclear Regulatory Commission regulations, and (b) satisfactorily complete a written examination covering these topics;

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

    a. Received training in the topics set forth in 180 NAC 5-016.07 or equivalent State or U.S. Nuclear Regulatory Commission regulations;

    b. Satisfactorily completed a minimum period of on the job training as specified in180 NAC 5-016.01 and

    c. Received verification by a State licensee or registrant or an U.S. Nuclear Regulatory Regulation licensee that the applicant has demonstrated the capability of independently working as a radiographer.

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5. Provide a certification period of not less than 3 years nor more than 5 years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in 180 NAC 5-016.07 or equivalent State or U.S. Nuclear Regulatory Commission requirements;

    2. Written in multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in180 NAC 5-016.07.

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ATTACHMENT

Attachment Number 6-1 Public Law 90-602, the Radiation Control for Health and Safety Act of 1968

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TITLE 180 CONTROL OF RADIATION

CHAPTER 6 X-RAYS IN THE HEALING ARTS

6-001 SCOPE AND AUTHORITY

6-001.01 180 NAC 6 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. sections 71-3501 to 3519.

6-001.02 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment shall be by or under the supervision of one licensed to practice the healing arts in Nebraska.

6-001.03 The use of x-ray equipment in the practice of veterinary medicine shall be by or under the supervision of an individual authorized to practice veterinary medicine in the State of Nebraska.

6-001.04 The provisions of 180 NAC 6 are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 16, 17 and 18.

6-002 DEFINITIONS: As used in Title 180, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Added filtration means any filtration which is in addition to the inherent filtration.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

Assembler means any person assembling, replacing, or installing one or more components into an x-ray system or subsystem. It includes adjustment of components which affect output of radiation

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.

generating equipment. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also"Phototimer")

Barrier (See "Protective barrier").

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam monitoring system means a system designed to detect and measure the radiation present in the useful beam.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 6-1 and incorporated herein by this reference.

Certified system means any x-ray system which has one or more certified component(s).

Changeable filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}\right]^{1/2}$$

[2]Ibid.

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Computed tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Contact therapy system means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.
Cooling curve means the graphical relationship between heat units stored and cooling time.
"CT" (See "Computed tomography").

Deadman switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector (See Radiation detector).

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

Entrance exposure rate means the exposure per unit time at the point where the center of the useful beam enters the patient.

Equipment (See "X-ray equipment").

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield means a protective barrier for the testes or ovaries.

Half-value layer means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

HVL (See "Half-value layer").

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Image receptor support means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Irradiation means the exposure of matter to ionizing radiation.

Kilovolts peak (See "Peak tube potential").

kV means kilovolts.

kVp (See Peak tube potential).

kWs means kilowatt second. It is equivalent to E + 3 kV mA s, i.e.,

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{\frac{E+3}{kV \times mA \times s}} = \frac{XYZ\ kWs}{E+3}$$

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

Leakage technique factors means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = 100 $(V_n-V_1)/V_1$ where
V_n = No-load line potential and
V_1 = Load line potential

Linear attenuation coefficient or u means the quotient of dN/N divided by d1 when dN/N is the fraction of unchanged ionizing radiation that experience interactions in traversing a distance d1 in a specified material.

uC/kg means microcoulomb/kilogram.

mA means milliampere.

mAs means milliampere second.

mC/kg means millicoulomb/kilogram.

Maximum line current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile x-ray equipment (See X-ray equipment).

nC/kg means nanocoulomb/kilogram.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Phototimer means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

PID (See "Position indicating device").

Portable x-ray equipment (See X-ray equipment).

Position indicating device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier (See Protective barrier).

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

Primary protective barrier means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Qualified expert with reference to radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons certified in this field by the American Board of Radiology, or the American Board of Health Physics, or those having equivalent qualifications). With reference to the calibration of radiation therapy equipment, a person having in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications) or meets the minimum qualifications specified in 180 NAC 15-013.03.

Radiation detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation therapy simulation system means a fluoroscopic or radiographic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographic imaging system means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Radiological physicist means an individual who meets the requirements of 180 NAC 15-013.01 Radiological Medical Physicist or 180 NAC 15-013.02 Radiological Health Physicist.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons.

Response time means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

Secondary dose monitoring system means a system which will terminate irradiation in the event of failure of the primary system.

Secondary protective barrier (See "Protective barrier").

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (See Source-image receptor distance).

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Special purpose x-Ray system means any radiographic x-ray system which, by design, is limited to radiographic examination of a specific anatomical region.

Spot check means a procedure which is performed to assure that a previous calibration continues to be valid.

Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD means the distance between the source and the skin of the patient.

Stationary x-ray equipment (See X-ray equipment).

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

3. For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5 For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Termination of irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Traceable to a national standard means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Variable-aperture beam-limiting device means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Wedge filter means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays, including, but not limited to, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system shall be considered integral parts of the system.

X-ray subsystem means any combination of two or more components of an x-ray system.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

6-003 GENERAL REQUIREMENTS

6-003.01 Administrative Controls

1. Registrant: The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 180 NAC 6-003.01, item 1. are met in the operation of the x-ray system(s).

    a. An x-ray system which does not meet the provisions of Title 180 shall not be operated for diagnostic or therapeutic purposes, unless the Agency makes a finding that its continued use will not constitute a risk to the health and safety of the public.
    b. Registrants shall assure that individuals who will operate x-ray systems under the direction of healing arts practitioners shall meet the requirements as specified in 180 NAC 16. The Limited X-Ray System Operator shall be instructed in the radiation safety and use of the x-ray equipment as specified in 180 NAC 16-005.
    c. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information.

        (1) Patient's anatomical size versus technique factors to be utilized;
        (2) Type and focal distance of the grid to be used, if any;
        (3) Source to image receptor distance to be used;
        (4) Type and location of placement of gonad shielding to be used; and
        (5) Type and size of the film or film-screen combination to be used.

    d. Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(1) Doors that are an integral part of room shielding shall be closed during x-ray procedures; and
(2) The door in 180 NAC 6-003.01, item 1.d.(1). shall be posted "Close door during x-ray procedures".

e. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
(2) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
(3) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

f. Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

g. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and
(2) Exposure of an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.01,I item 1.k.

h. When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 180 NAC 6-003.01, item 1., d., shall list projections where holding devices cannot be utilized;
(2) The human holder shall be protected as required by 180 NAC 6-003, item 1.e.;
(3) No individual shall be used routinely to hold film or patients;

(4) Written safety procedures, as required by 180 NAC 6-003.01 ,item 1.d.; shall indicate the requirements for selecting a holder and the procedure the holder shall follow; and

(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

i. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
(2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
(3) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.
(4) X-ray systems subject to 180 NAC 6-006 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

j. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 180 NAC 4-005, 4-050 and 4-022. In addition: Deleted: 48

(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(a) When an apron is worn, the monitoring device shall be worn at the collar outside the apron.
(b) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by 180 NAC 4-052. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body. Deleted: 0

(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

k. Healing Arts Screening: Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix A of 180 NAC 6. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

2. Information and Maintenance Record and Associated Information: The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

   a. Model and serial numbers of all certifiable components;
   b. Aluminum equivalent filtration of the useful beam, including any routine variation;
   c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after June 27, 1983 with the names of persons who performed such services.
   d. A scale drawing shall be available of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

      (1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
      (2) The type and thickness of materials, or lead equivalency, of each protective barrier; and

   e. A copy of all correspondence with this Agency regarding that x-ray system.

6-003.02 X-Ray Log: Each facility shall maintain an x-ray log or chart containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

6-003.03 Plan Review

1. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to a qualified expert or the Agency for review and comment. The required information is denoted in Appendices 2 and 3 of 180 NAC 6.
2. The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and comment. For particle accelerator facilities the qualified expert shall be a radiological physicist.
3 The review of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 and 4-013.

6-004 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS: In addition to other requirements of 180 NAC 6-004 all diagnostic x-ray systems shall meet the following requirements:

6-004.01 Warning Label: The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

6-004.02 Battery Charge Indicator: On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6-004.03 Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of I meter in any direction from the source shall not exceed 100 milliroentgens (25.8 uC/kg) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.04 Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 uC/kg) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.05 Beam Quality

1. Half-value Layer

   a. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design operating range (kVp)	Measured Potential (kVp)	Half-value layer (mm of aluminum)
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

b. The requirements of 180 NAC 6-004.05, item 1.a. will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

c. In addition to the requirements of 180 NAC 6-004.05, item 1.a. all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

d. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

e. For capacitor energy storage equipment, compliance with the requirements of 180 NAC 6-004.05 shall be determined with the maximum quantity of charge per exposure.

f. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls: For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 180 NAC 6-004.05, item 1.a. is in the useful beam for the given kVp which has been selected.

6-004.06 Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6-004.07 Mechanical Support of Tube Head: The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.

6-004.08 Technique Indicators

1. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
2. The requirement of 180 NAC 6-004.08, item 1. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

6-004.09 Structural Shielding: Structural shielding shall be provided as necessary to meet the requirements of 180 NAC 4-005, 4-022, and 4-013.

6-005 FLUOROSCOPIC X-RAY SYSTEMS: All fluoroscopic x-ray systems shall meet the following requirements:

6-005.01 Limitation of Useful Beam

1. Primary Barrier

   a. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID.
   b The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

2. X-Ray Field

   a. Use of nonimage-intensified fluoroscopic equipment shall not be used.
   b. For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

      (1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;
      (2) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 by 5 centimeters or less;
      (3) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means

shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

(4) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image receptor, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

c. Spot-film devices which are certified components shall meet the following additional requirements, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished when the x-ray field size in the plane of the film is greater than that of the selected portion of the film. If the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(2) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

(3) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

(4) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6-005.02 Activation of the Fluoroscopic Tube: X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6-005.03 Exposure Rate Limits

1. Entrance Exposure Rate Allowable Limits

a. The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens (2.58 mC/kg) per

minute, except during recording of fluoroscopic images or when provided with optional high level control.

b When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

(1) Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.
(2) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

c. In addition to the other requirements of 180 NAC 6-005, certified systems which do not incorporate an automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.

d. Compliance with the requirements of 180 NAC 6-005.03 shall be determined as follows:

(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.
(2) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.
(3) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
(4) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

e. Periodic measurement of entrance exposure rate shall be performed as follows:

(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
(2) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 180 NAC 6-003.01, item 2., c. The measurement results shall be stated in roentgens (C/kg) per minute and include the technique factors used in determining such results. The name of the person performing the measurements and

the date the measurements were performed shall be included in the results.

(3) Personnel monitoring devices may be used to perform the measurements required by 180 NAC 6-005.03, item 1.e.(1), provided the measurements are made as described in 180 NAC 6-005.03, item 1, e.(4).

(4) Conditions of periodic measurement of entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of 180 NAC 6-005.03, item 1.d.

(b) The kVp shall be the kVp typical of clinical use of the x-ray system;

(c) The x-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and

(d) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.[3]

6-005.04 Barrier Transmitted Radiation Rate Limits

1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

2. Measuring Compliance of Barrier Transmission

a. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

b. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

c. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

[3]Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

d. Movable grids and compression devices shall be removed from the useful beam during the measurement.
e. The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly. Closer distances may be used if corrections are applied for poor geometry.

6-005.05 Indication of Potential and Current: During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

6-005.06 Source-to-Skin Distance: The SSD shall not be less than:

1. 38 centimeters on stationary fluoroscopes installed after June 27, 1983,
2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to November 23, 1990.
3. 30 centimeters on all mobile fluoroscopes, and
4. 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

6-005.07. Fluoroscopic Timer

1. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.
2. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. As an alternative to the requirements of this subpart, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between examinations.
3. The total time of exposure shall be recorded.

6-005.08 Mobile Fluoroscopes: In addition to the other requirements of 180 NAC 6-005, mobile fluoroscopes shall provide intensified imaging.

6-005.09 Control of Scattered Radiation

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

    a. Is at least 120 centimeters from the center of the useful beam, or

b. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, (drapes, Bucky-slot cover panel, or self-supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in 180 NAC 6-003.01, item 1.e.

3. The Agency may grant exceptions to 180 NAC 6-005.09, item 2., where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

6-005.10 Radiation Therapy Simulation Systems: Radiation therapy simulation systems shall be exempt from all the requirements of 180 NAC 6-005.01, 6-005.03, 6-005.04, and 6-005.07 provided that:

1. Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
2. Systems which do not meet the requirements of 180 NAC 6-005.07 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

6-006 RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, VETERINARIAN, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS:

6-006.01 Beam Limitation: The useful beam shall be limited to the area of clinical interest.

1. General Purpose Stationary and Mobile X-Ray Systems

   a. There shall be provided a means for stepless adjustment of the size of the x-ray field.
   b. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
   c. The Agency may grant an exemption on non-certified x-ray systems to 180 NAC 6-006.01, item 1.a. and b. provided the registrant makes a written application for such exemption and in that application:
      (1) Demonstrates it is impractical to comply with 180 NAC 6-006.01, item 1.a. and b.
      (2) The purpose of 180 NAC 6-006.01, item 1.a. and b. will be met by other methods.

2. Additional Requirements for Stationary General Purpose X-Ray Systems: In addition to the requirements of 180 NAC 6-006.01, item 1., all stationary general purpose x-ray systems shall meet the following requirements:

a. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;
b. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
c. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X-Ray Systems Designed for One Image Receptor Size: Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
4. Systems Designed for or Provided with Special Attachments for Mammography: Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in 180 NAC 6-006.01, item 5.c. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in 180 NAC 6-006.01, item 5.c.(1). and (2). shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

5. Special Purpose X-Ray Systems

a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the

plane of the image receptor does not extend beyond any edge of the image receptor.

c. 180 NAC 6-006.01, item 5.a. and b. may be met with a system that meets the requirements for a general purpose x-ray system as specified in 180 NAC 6-006.01, item 1. or, when alignment means are also provided, may be met with either:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

6-006.02 Radiation Exposure Control Devices

1. Timers: Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. X-Ray Control

a. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposures of one-half (1/2) second or less, or

(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

b. Each x-ray control shall be located in such a way as to meet the following requirements:

(1) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(2) Mobile and portable x-ray systems which are:

(a) Used in one location, i.e., a room or suite, shall meet the requirements of subdivision 180 NAC 6-006.02, item 2.b.(1).

(b) Used in different locations shall provide operator protection at the controls by adequate shielding or operator positioning at a distance from the tube head of 12 feet (3.66m).

(3) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Automatic Exposure Controls: When an automatic exposure control is provided:

a. Indication shall be made on the control panel when this mode of operation is selected;
b. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;
c. The minimum exposure time for all equipment other than that specified in 180 NAC 6-006.02, item 3.b. shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;
d. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
e. A visible signal shall indicate when an exposure has been terminated at the limits required by 180 NAC 6-006.02, item 3.d. and manual resetting shall be required before further automatically timed exposures can be made.

4. Reproducibility: With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed.

$$T \geq 5(T_{max} - T_{min})$$

6-006.03 Source-to-Skin Distance: All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeters.

6-006.04 Exposure Reproducibility: The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5(E_{max} - E_{min})$$

6-006.05 Radiation from Capacitor Energy Storage Equipment in Standby Status: Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 uC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6-006.06 Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility: When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity: When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|X_1 - X_2| \leq 0.10 (X_1 + X_2)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs (uC/kg per mAs) values obtained at each of 2 consecutive tube current settings.

3. Accuracy: Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems:

   a. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.
   b. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.
   c. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of

beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as $1_1/1_2$ where 1_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and 1_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

5. Beam Limitation for Portable X-Ray Systems: Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 180 NAC 6-006.01, item 1. and 180 NAC 6-006.06, item 4.

6. Field Limitation and Alignment on Stationary General Purpose X-Ray Systems: The requirements of this subpart shall apply to stationary general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c).

   a. Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:
      (1) The image receptor is inserted into a permanently mounted cassette holder;
      (2) The image receptor length and width are each less than 50 centimeters;
      (3) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;
      (4) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;
      (5) Neither tomographic nor stereographic radiography is being performed, and
      (6) The PBL system has not been intentionally overridden. This override provision is subject to 180 NAC 6-006.06, item 6.c.

   b. Positive beam limitation (PBL) shall prevent the production of x-rays when:

      (1) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 180 NAC 6-006.06, item 6.e., from the corresponding image receptor dimensions by more than 3 percent of the SID; or
      (2) The sum of the length and width differences as stated in 180 NAC 6-006.06, item 6.b.(1), without regard to sign exceeds 4 percent of the SID.

   c. If a means of overriding the positive beam limitation (PBL) system exists, that means:

      (1) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

(2) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator;

(a) Shall require that a key be utilized to defeat the PBL;
(b) Shall require that the key remain in place during the entire time the PBL system is overridden; and
(c) Shall require that the key or key switch be clearly and durably labeled as follows:
FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

d. Compliance with 180 NAC 6-006.06, item 6.b. shall be determinedwhen the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 180 NAC 6-006.06, item a. are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

e. The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

f. The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in 180 NAC 6-006.06, item 6.b. then any change of image receptor size or SID must cause the automatic return.

7. Timers: Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

a. Except during serial radiography, the operator shall be able to terminate the exposure at anytime during an exposure of greater than one-half second. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

8. Transmission Limit for Image Receptor Supporting Devices Used for Mammography: For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over

an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-007 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS: In addition to the provisions of 180 NAC 6-003 and 6-004, the requirements of 180 NAC 6-007 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 180 NAC 6-006.

6-007.01 Source-to-Skin Distance: X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

1. 18 centimeters if operable above 50 kVp, or
2. 10 centimeters if not operable above 50 kVp.

6-007.02 Field Limitation

1. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

   a. If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and
   b. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

2. An open ended position indicating device shall meet the requirements of 180 NAC 6-004.03.

6-007.03 Timers: Means shall be provided to terminate the exposure at the preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

1. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
2. Reproducibility. With a timer setting of 0.5 seconds or, not less than 0.1 second, the average exposure period ($\bar{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed;

$$\bar{T} \geq 5 (T_{max} - T_{min})$$

6-007.04 X-Ray Control

1. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

2. Each x-ray control shall be located in such a way as to meet the following requirements:

   a. Stationary x-ray systems installed after June 27, 1983 shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in the protected area during the entire exposure; and
   b. Stationary x-ray systems installed prior to June 27, 1983, the operator shall remain in a protected area which permits compliance with 180 NAC 4-005 4-022, and 4-013 and
   c. Mobile and portable x-ray systems which are:

      (1) Used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of 180 NAC 6-007.04, item 2. a. and 6-007.04, item 2.b.; or
      (2) Used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of 180 NAC 6-007.04, item 2.c.(1) or be provided with a 6.5 feet (1.98m) high protective barrier which is placed at least 6 feet (1.83m) from the tube housing assembly and at least 6 feet (1.83m) from the patient; or
      (3) Used to make an exposure(s) of a patient at the use location shall meet the requirement of 180 NAC 6-007.04, item 2. c. (1) or (2) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66m) from the tube housing assembly during an exposure.
      (4) For those x-ray systems used infrequently to make an exposure(s) of a patient at the use location, it shall be provided with a method of x-ray control which will permit the operator to be at least 6 feet (1.83m) from the tube housing assembly or the patient and be out of the primary beam during the exposure.

3. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6-007.05 Exposure Reproducibility: The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{max}):

$$\bar{E} \geq 5 (E_{max} - E_{min})$$

6-007.06 Administrative Controls

1. Patient and film holding devices shall be used when the techniques permit.

2. The tube housing and the position indicating device shall not be hand-held during an exposure.
3. For intraoral radiography, the x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 180 NAC 6-007.02, item 1.
4. Dental fluoroscopy without image intensification shall not be used.

6-007.07 Additional Requirements Applicable to Certified Systems Only: Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left| \bar{X}_1 - \bar{X}_2 \right| \leq 0.10 \left(\bar{X}_1 + \bar{X}_2 \right)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.
3. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
5. Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 180 NAC 6-004.05, item 1.

6-008 THERAPEUTIC X-RAY SYSTEMS OF LESS THAN ONE MEV

6-008.01 Equipment Requirements

1. Leakage Radiation: When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

    a. Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 uC/kg) per hour at 5 centimeters from the surface of the tube housing assembly.

b. 0-l50 kVp Systems. Systems which were manufactured prior to June 27, 1983 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.
c. 0-150 kVp Systems. Systems which are manufactured on or after June 27, 1983 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 uC/kg) in 1 hour at 1 meter from the source.
d. 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.

2. Permanent Beam Limiting Devices: Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.
3. Removable and Adjustable Beam Limiting Devices

a. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
b. Adjustable beam limiting devices installed after the effective date of Title 180 shall meet the requirements of 180 NAC 6-008.01, item 3.a.
c. Adjustable beam limiting devices manufactured prior to August 1, 1974 and installed before the effective date of Title 180 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

4. Filter System: The filter system shall be so designed that:

a. Filters cannot be accidently displaced at any possible tube orientation;
b. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and
c. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions.

5. Tube Immobilization: The tube housing assembly shall be capable of being immobilized for stationary treatments.
6. Focal Spot Marking: The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.
7. Beam Block: Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be

positioned over the entire useful beam exit port during periods when the beam is not in use.

8. Reserved

9. Timer

   a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
   b. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
   c. The timer shall terminate irradiation when a pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
   d. The timer shall permit accurate presetting and determination of exposure times as short as 1 second.
   e. The timer shall not permit an exposure if set at zero.
   f. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

10. Control Panel Functions: The control panel, in addition to the displays required in other provisions of 180 NAC 6-008, shall have:

    a. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
    b. An indication of whether x-rays are being produced;
    c. Means for indicating x-ray tube potential and current;
    d. The means for terminating an exposure at any time;
    e. A locking device which will prevent unauthorized use of the x-ray system; and
    f. For x-ray equipment manufactured after June 27, 1983, shall have a positive display of specific filter(s) in the beam.

11. Multiple Tubes: When a control panel may energize more than one x-ray tube:

    a. It shall be possible to activate only one x-ray tube during any time interval;
    b. There shall be an indication at the control panel identifying which x-ray tube is energized; and
    c. There shall be an indication at the tube housing assembly when that tube is energized.

12. Source-to-Skin Distance: There shall be means of determining the source-to-skin distance to within 1 centimeter.

13. Shutters: Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,

a. After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
b. An indication of shutter position shall appear at the control panel.

14. Low-Filtration X-Ray Tubes: Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

6-008.02 Facility Design Requirements for X-Ray Systems Capable of Operating Above 50 kVp: In addition to shielding adequate to meet requirements of 180 NAC 4 and 180 NAC 6, the treatment room shall meet the following design requirements:

1. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
2. Viewing Systems.

a. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

b. When the primary viewing system is by electronic means an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

3. Additional Requirements for X-Ray Systems Capable of Operation Above 150 kVp.

a. All protective barriers shall be fixed except for entrance doors or beam interceptors.
b. The control panel shall be located outside the treatment room.
c. Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
d. When any door referred to in 180 NAC 6-008.02, item 3.c. is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8 uC/kg) per hour.

6-008.03 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
b. The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.
c. The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist is in violation of applicable regulations.

2. Calibrations

a. The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
b. The calibration of the x-ray system shall be performed by a radiological physicist.
c. The calibration of radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding 2 years.
d. The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to an accuracy within $\pm$ 5 percent.
e. The calibration of the x-ray system shall include, but not be limited to, the following determinations:

(1) Verification that the x-ray system is operating in compliance with the design specifications;
(2) The exposure rates as a function of field size, technique factors, filter, and treatment distance used;
(3) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
(4) An evaluation of the uniformity of the largest radiation field used.

f. Records of calibration shall be maintained by the registrant for 5 years after completion of the calibration.
g. A copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

3. Spot Checks: Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

a. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be available to the Agency.

b. If a radiological physicist does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

c. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in 180 NAC 6-008.03, item 2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in 180 NAC 6-008.03, item 2., shall be stated.

d. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

e. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist spot-check procedures, the system shall be recalibrated as required in 180 NAC 6-008.03, item 2.

f. Records of spot-check measurements shall be maintained by the registrant for 5 years after completion of the spot-check measurements and any necessary corrective actions.

g. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 006.08C2 or which has been intercompared with a system meeting those requirements within the previous year.

4. Operating Procedures

a. X-ray systems shall not be left unattended unless the system is secured against unauthorized use.

b. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

c. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

d. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 180 NAC 4-006. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.

e. No person shall operate an accelerator until they meet the training requirements of 180 NAC 15-024.

f. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of 180 NAC 6-008.03, item 2. and 180 NAC 6-008.03, item 3.e. have been met.

6-009 X-RAY AND ELECTRON THERAPY SYSTEMS WITH ENERGIES OF ONE MEV AND ABOVE: 180 NAC 9 except 180 NAC 9-011.03 and 180 NAC 9-011.04 shall apply to medical facilities using therapy systems with energies 1 MeV and above:

6-009.01 Definitions: In addition to the definitions provided in 180 NAC 6-002, the following definitions shall be applicable to 180 NAC 6-009:

1. "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.
2. "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
3. "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.
4. "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.
5. "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
6. "Existing equipment" means therapy systems subject to 180 NAC 6-009 which were manufactured on or before January 1, 1985.
7. "Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.
8. "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.
9. "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
10. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
11. "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.
12. "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.
13. "New equipment" means systems subject to 180 NAC 6-009 which were manufactured after January 1, 1985.
14. "Normal treatment distance" means:

    (a) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
    (b) For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

15. "Radiation head" means the structure from which the useful beam emerges.

16. "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.
17. "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.
18. "Target" means that part of a radiation head source which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.
19. "Virtual source" means a point from which radiation appears to originate.

6-009.02 Requirements for Equipment

1. Leakage Radiation to the Patient Area

a. New equipment shall meet the following requirements:

(1) For operating conditions, producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 180 NAC 6-009.02, item 1.a.(1) for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

b. Existing equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meter radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified

in 180 NAC 6-009.02, item 1.b.(1) for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

2. Leakage Radiation Outside the Patient Area for New Equipment

   a. The absorbed dose in rads (grays) due to leakage radiation except in the area specified in 180 NAC 6-009.02, item 1.a.(1) when measured at any point I meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in 180 NAC 6-009.02, item 1.a.(1).
   b. The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 180 NAC 6-009.02, item 2.a. for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

3. Beam Limiting Devices: Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.

4. Filters

   a. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
   b. If the absorbed dose rate data required by 180 NAC 6-009.02, item 16., relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
   c. For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
      (1) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
      (2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position; and
      (3) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

5. Beam Quality: The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

   a. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

   b. Compliance with 180 NAC 6-009.02, item 5.a. shall be determine using:

      (1) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
      (2) The largest field size available which does not exceed 15 by 15 centimeters; and
      (3) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

   c. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

d. Compliance with 180 NAC 6-009.02, item 5.c. shall be determined by measurements made:

(1) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
(2) Using a phantom whose size and placement meet the requirements of 180 NAC 6-009.02, item 5.b.;
(3) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
(4) Using the largest field size available which does not exceed 15 by 15 centimeters.

e. The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

6. Beam Monitors: All therapy systems shall be provided with radiation detectors in the radiation head.

a. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
b. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
c. The detectors and the system into which that detector is incorporated shall meet the following requirements:

(1) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(2) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
(3) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.
(4) For new equipment, the design of the dose monitoring systems shall assure that:

(a) The malfunctioning of one system shall not affect the correct functioning of the second system; and
(b) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

(5) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

(a) Maintain a reading until intentionally reset to zero;
(b) Have only one scale and no scale multiplying factors;
(c) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdoseage of radiation, the absorbed dose may be accurately determined; and
(d) In the event of power failure, the dose monitoring information required in 180 NAC 6-009.02, item 6.c.(5) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

7. Beam Symmetry: In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

8. Selection and Display of Dose Monitor Units

a. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
b. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.
c. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.
d. For new equipment after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

9. Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy

   a. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
   b. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
   c. For new equipment, a second dose monitoring system shall be present. The system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
   d. For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

10. Interruption Switches: It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

11. Termination Switches: It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

12. Timer

   a. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
   b. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
   c. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
   d. For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

13. Selection of Radiation Type: Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

a. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
b. An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
d. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
e. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
f. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

14. Selection of Energy: Equipment capable of generating radiation beams of different energies shall meet the following requirements:

a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
c. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
d. For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

15. Selection of Stationary Beam Therapy or Moving Beam Therapy: Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

a. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
b. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
d. For new equipment, an interlock system shall be provided to terminate irradiation if:

(1) Movement of the gantry occurs during stationary beam therapy; or
(2) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

e. Moving beam therapy shall be so controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(1) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.
(2) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

f. The mode of operation shall be displayed at the treatment control panel.
g. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 180 NAC 6-009.02, item 9.

16. Absorbed Dose Rate Monitor: For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.[4] In addition:

a. The dose monitor unit rate shall be displayed at the treatment control panel.
b. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

17. Location of Virtual Source and Beam Orientation: The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

a. The x-ray target or the virtual source of x-rays; and
b. The electron window or the virtual source of electrons if the system has electron beam capabilities.

6-009.03 Facility and Shielding Requirements: In addition to 180 NAC 4, the following design requirements shall apply:

1. Protective Barriers: All protective barriers shall be fixed except for entrance doors or beam interceptors.
2. Control Panel: The control panel shall be located outside the treatment room.
3. Viewing Systems

[4]The radiation detectors specified in 6-009.02, item 6 may form part of this system.

a. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
b. When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

4. Aural Communications: Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.
5. Room Entrances: Treatment room entrances shall be provided with warning lights, in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".
6. Entrance Interlocks: Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6-009.04 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
b. The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.
c. The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist is in violation of applicable regulations.

2. Calibrations

a. The calibration of systems subject to 180 NAC 6-009 shall be performed in accordance with an established calibration protocol acceptable to the Agency[5] before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any

[5]The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the Agency for concurrence that the protocol is acceptable.

change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

b. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.

c. Calibration radiation measurements required by 180 NAC 6-009.04, item 2. a. shall be performed using a dosimetry system:

(1) Having a calibration factor for cobalt-60 gamma rays traceable to a national standard;
(2) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
(3) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
(4) Which has had constancy checks performed on the system as specified by a radiological physicist.

d. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an accuracy of $\pm$ 5 percent.

e. The calibration of the therapy beam shall include but not be limited to the following determinations:

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.
(2) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
(3) The uniformity of the radiation field and any dependency upon the direction of the useful beam.
(4) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
(5) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

f. Records of calibration measurements under 180 NAC 6-009.04, item 2. a. and dosimetry system calibrations under 180 NAC 6-009.04, item 2.c. shall be maintained for 5 years after completion of the full calibration.

g. A copy of the latest calibration performed pursuant to 180 NAC 6-009.04, item 2 a. shall be available in the area of the control panel.

3. Spot checks: Spot checks shall be performed on systems subject to 180 NAC 6-009 during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements.

a. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the Agency prior to its implementation.
b. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
c. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.
d. At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom for photon beams.
e. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
f. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
g. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in 180 NAC 6-009.04, item 2.
h. Records of spot-check measurements shall be maintained by the registrant for a period of 5 years after completion of the spot-check measurements and any necessary corrective actions.
i. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 180 NAC 6-009.04, items 1. 2. and 3. or which has been intercompared with a system meeting those requirements within the previous year.

4. Operating Procedures:

a. No individual other than the patient shall be in the treatment room during treatment of a patient.
b. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
c. No person shall operate an accelerator until they meet the training and experience requirements of 180 NAC 15-021.
d. The system shall not be used in the administration of radiation therapy unless the requirements of 180 NAC 6-009.04, item 1., 2. and 3. have been met.

6-010 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

6-010.01 Equipment

1. The protective tube housing shall be equivalent to the requirements of 180 NAC 6-004.03.
2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.
3. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.
4. A device shall be provided to terminate the exposure after a preset time or exposure.
5. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83m) from the animal during all x-ray exposures.

6-010.02 Structural Shielding: All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 180 NAC 4-005, 4-011, and 4-013.

6-010.03 Operating Procedures

1. The operator shall be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.
2. No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.
3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.
4. Veterinary Assistant's Training Requirements. Effective November 15, 1990, veterinary assistant's shall have eight (8) hours of classroom instruction in the fundamentals of radiation safety, radiation detection instrumentation, radiographic equipment, state and federal regulations, operating and emergency procedures and case histories of radiography accidents as outlined in 180 NAC 15-024, "Minimum Training Requirements for Operators of Non-Human X-Ray" of Title 180.

6-011 COMPUTED TOMOGRAPHY SYSTEMS

6-011.01 Definitions: In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions shall be applicable to 180 NAC 6-011:

1. "Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the

product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-nT}^{+nT} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

2. "CTDI" (See "Computed tomography dose index").
3. "Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{u_x - u_w}{(CTN)_x - (CTN)_w}$$

where:

u_x = Linear attenuation coefficient of the material interest.
u_w = Linear attenuation coefficient of water. $(CTN)_x$ = CTN of the material of interest.
$(CTN)_w$ = CTN of water.

4. "CS" (See "Contrast scale").
5. "CT conditions of operation" means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 180 NAC 6-002.
6. "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.
7. "CTN" (See "CT number").
8. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(u_x - u_w)}{u_w}$$

where:

k = A constant[6]
u_x= Linear attenuation coefficient of the material of interest.
u_w= Linear attenuation coefficient of water.

9. "Dose profile" means the dose as a function of position along a line.

10. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").
11. "Multiple tomogram system" means a system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.
12. "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (s_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{u_w}$$

where:

CS = Contrast scale
u_w = Linear attenuation coefficient of water.
s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

13. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.
14. "Picture element" means an elemental area of a tomogram.
15. "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.
16. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.
17. "Scan increment" means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.
18. "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.
19. "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.
20. "Single tomogram system" means a CT system which obtains x-ray transmission data during a scan to produce a single tomogram.
21. "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

[6]The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.

22. "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

6-011.02 Requirements for Equipment

1. Termination of Exposure

   a. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.
   b. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 180 NAC 6-011.02, item 1.a.
   c. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half second duration.

2. Tomographic Plane Indication and Alignment

   a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
   b. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.
   c. If a device using a light source is used to satisfy 180 NAC 6-011.02, item 2.a. or b., the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and Shutter Status Indicators and Control Switches

   a. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
   b. Each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT Conditions of Operation: The CT System shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
5. Entraneous Radiation: When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 180 NAC 6-004.03.

6. Maximum Surface CTDI Identification: The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.
7. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985

   a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.
   b. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
   c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass of 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

   d. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

6-011.03 Facility Design Requirements.

1. Aural Communication Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
2. Viewing Systems

   a. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
   b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

6-011.04 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

   a. All CT x-ray systems installed after the effective date of Title 180 and those systems not previously surveyed shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

b. The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be made available to the Agency upon request.

2. Radiation Calibrations

a. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a radiological physicist.
b. The calibration of a CT x-ray system shall be performed at intervals specified by a radiological physicist and after any change or replacement of components which, in the opinion of the radiological physicist could cause a change in the radiation output.
c. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.
d. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.
(2) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.
(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.
(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.
f. Calibration shall meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be

measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

(2) The CTDI[7] along the two axes specified in 180 NAC 6-011.04, item 2.d.(2) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

(3) The spot checks specified in 180 NAC 6-011.04, item 3. shall be made.

g. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

3. Spot Checks

a. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.

b. The spot-check procedures shall incorporate the use of a CT phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

c. All spot checks shall be included in the calibration required by 180 NAC 6-011.04, item 2. and at time intervals and under system conditions specified by a radiological physicist.

d. Spot checks shall include acquisition of images obtained with the CT phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 180 NAC 6-011.04, item 2. The images shall be retained, until a new calibration is performed, in two forms as follows:

(1) Photographic copies of the images obtained from the image display device; and

(2) Images sorted in digital form on a storage medium compatible with the CT x-ray system.

e. Written records of the spot checks performed shall be maintained for inspection by the Agency.

4. Operating Procedures

[7]For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

a. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

b. Information shall be available in the control area regarding the operation and calibration of the system. Such information shall include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system.

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the radiological physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the radiological physicist.

APPENDIX 6-A
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and adddress of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

3. Description in detail of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of Title 180.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of each individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

APPENDIX 6-B

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

1. The plans should show, as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

APPENDIX 6-C

DESIGN RECOMMENDATIONS FOR AN OPERATOR'S BOOTH

1. Space Requirements:

   (a) The operator shall be allotted not less than 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

   (b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

   (c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

   (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.

2. Structural Requirements:

   (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

   (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

   (c) Shielding shall be provided to meet the requirements of 180 NAC 4.

3. X-Ray Control Placement:

   The x-ray control for the system shall be fixed within the booth and:

   (a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table.

   (b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

   (a) Each booth shall have at least one viewing device which will:

      (1) Be so placed that the operator can view the patient during any exposure, and

      (2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room can not be seen from the booth, then that door

must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) It shall have a viewing area of at least 1 square foot (0.0929m^2) with the lower edge of the window at least 4.5 feet (1.37m) above the floor.

(2) The distance between the nearest edge of the window and the open edge of the booth shall not be less than 18 inches (0.457m).

(3) The glass shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 180 NAC 6, Appendix 6-B, 4.(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of 180 NAC 6, Appendix 6-C, 4.(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

ATTACHMENT 6-1

Public Law 90-602, the Radiation Control for Health and Safety Act of 1968

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FORM(S)

Form NRH-5A Application for Radioactive Material License – Medical or Teletherapy

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TITLE 180 CONTROL OF RADIATION

CHAPTER 7 MEDICAL USE OF RADIOACTIVE MATERIAL

GENERAL INFORMATION

7-001 SCOPE AND AUTHORITY: 180 NAC 7 establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of 180 NAC 7 are in addition to, and not in substitution for, others in Title 180. The requirements and provisions of 180 NAC 1, 3, 4, 10, 13, 15, 17, and 18 apply to applicants and licensees subject to 180 NAC 7 unless specifically exempted. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 3519.

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

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

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

Authorized nuclear pharmacist means a pharmacist who is:

1. Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
2. Identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or
3. Identified as an authorized nuclear pharmacist on a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

Authorized user means a physician who meets the training and experience requirements in 180 NAC 7-066.02, 7-066.03, 7-066.04, 7-066.06, 7-066.08, or 7-066.09 and who is identified as an authorized user on an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

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Brachytherapy means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application."Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes

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

Management means the chief executive officer or that individual's designee.

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

Medical use means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

Misadministration means the administration of:

1. A radiopharmaceutical dosage greater than 1.11 MBq (30 microcuries) of either sodium iodide I-125 or I-131:

   a. Involving the wrong individual or wrong radiopharmaceutical, or
   b. When both the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 MBq (30 microcuries). Deleted: percent

2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

   a. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
   b. When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage. Deleted: percent

3. A gamma stereotactic radiosurgery radiation dose:

   a. Involving the wrong individual or wrong treatment site; or
   b. When the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose. Deleted: percent

4. A teletherapy radiation dose:

   a. Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
   b. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;
   c. When the calculated weekly administered dose is 30% greater than the weekly prescribed dose; or (d) when the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

5. A brachytherapy radiation dose:
   a. Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;
   b. Involving a sealed source that is leaking;
   c. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
   d. When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 MBq (30 microcuries) of either sodium iodide I-125 or I-131, both:

   a. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
   b. When the dose to the individual exceeds 50 mSv (5 rem) effective dose equivalent or 500 mSv (50 rem) dose equivalent to any individual organ.

Mobile nuclear medicine service means the transportation and medical use of radioactive material.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

Physician means someone licensed or otherwise authorized to perform medicine and surgery pursuant to Neb Rev. Stat. §§ 71-1, 102. to 71-1, 107.14 Neb. Rev. Stat. and §§ 71-1, 137 through 71-1, 141 of the Act.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

1. For gamma stereotactic radiosurgery, the total dose;
2. For teletherapy, the total dose and dose per fraction;

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3. For brachytherapy, either the total source strength and exposure time or the total dose.

Teletherapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Teletherapy physicist means the individual identified as the teletherapy physicist on an Agency license.

Written directive means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

1. For any administration of a quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
5. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
6. For all other brachytherapy:

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

7-003 PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS: A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee must apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees must, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

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7-004 FDA, FEDERAL AND STATE REQUIREMENTS: Nothing in this Chapter relieves the licensee from complying with applicable FDA, Federal, and State requirements governing radioactive drugs or devices.

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GENERAL REGULATORY REQUIREMENTS

7-005 LICENSE REQUIRED

7-005.01 A person must not manufacture, produce, acquire, receive, possess, own, use, transport, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to Title 180.

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7-005.02 Unless prohibited by license condition, an individual may manufacture, produce, acquire, receive, possess, own, use, transport, or transfer radioactive material in accordance with the regulations in 180 NAC 7 under the supervision of an authorized user as provided in 180 NAC 7-013.

7-005.03 Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with Title 180 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 180 NAC 7-013.

7-006 APPLICATION FOR LICENSE, AMENDMENT, OR RENEWAL

7-006.01 If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

7-006.02 An application for a license for medical use of radioactive material as described in 180 NAC 7-034, 7-036, 7-040, 7-044, and 7-046 must be made by filing an original and one copy of Form NRH-5A (Medical/Teletherapy), "Application for Radioactive Material License - Medical or Teletherapy". For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

7-006.03 An application for a license for medical use of radioactive material as described in 180 NAC 7-052 must be made by filing an original and one copy of Form NRH-5A (Medical/Teletherapy), "Application for Radioactive Material License - Medical or Teletherapy" and Form NRH-5A Supplement C, "Application for Radioactive Material License - Medical or Teletherapy Requirements Specific to Teletherapy". For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

7-006.04 For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to 180 NAC 1-012.

7-006.05 An applicant that satisfies the requirements specified in 180 NAC 3-013.02 may apply for a Type A specific license of broad scope.

7-007 LICENSE AMENDMENTS: A licensee must apply for and receive a license amendment

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7-007.01 Before using radioactive material for a method or type of medical use not permitted by the license issued under 180 NAC 7-007;

7-007.02 Before permitting anyone, to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

1. An authorized user certified by the organizations specified in 180 NAC 7-066.02, item 1., 7-066.03, item 1., 7-066.04, item 1., 7-066.06, item 1., 7-066.08, item 1., or 7-066.09, item 2.;
2. An authorized nuclear pharmacist certified by the organization specified in 180 NAC 7-001;
3. Identified as an authorized user or an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or
4. Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

7-007.03 Before changing a Radiation Safety Officer or Teletherapy Physicist;

7-007.04 Before receiving radioactive material in excess of the amount authorized, or radionuclide or form different than authorized on the license;

7-007.05 Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

7-006.06 Before changing statements, representations, and procedures which are incorporated into the license.

7-008 NOTIFICATIONS

7-008.01 A licensee must provide to the Agency a copy of the board certification, the Agency, U.S. Nuclear Regulatory Commission, or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 180 NAC 7-007.02, items 1. through 4. Deleted: shall

7-008.02 A licensee must notify the Agency by letter no later than 30 days after: Deleted: shall

1. An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or
2. The licensee's mailing address changes.

7-008.03 The licensee must mail documents required in this 180 NAC 7-008 to the appropriate address identified in 180 NAC 1-002. Deleted: shall

ADDITIONAL REQUIREMENTS

7-009 ALARA PROGRAM

7-009.01 Each licensee must develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in 180 NAC 1-002. Deleted: shall

7-009.02 To satisfy the requirement of 180 NAC 7-009.01:

1. At a medical institution, the management, Radiation Safety Officer, and all authorized users must participate in the establishment, implementation, and operation of the program as required by Title 180 or the Radiation Safety Committee; or Deleted: shall
2. For licensees that are not medical institutions, management and all authorized users must participate in the program as required by the Radiation Safety Officer. Deleted: shall

7-009.03 The program must include notice to workers of the program's existence and workers responsibility to help keep dose equivalents ALARA, a review of the summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety measures, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make every reasonable effort to maintain individual and collective occupational doses ALARA.

7-009.04 The licensee must retain a current written description of the ALARA program for the duration of the license. The written description must include: Deleted: shall Deleted: shall

1. A commitment by management to keep occupational doses as low as reasonably achievable;
2. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;
3. Personnel exposure investigational levels as established in accordance with 180 NAC 7-011.02, item 8. that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and
4. Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

7-010 RADIATION SAFETY OFFICER

7-010.01 A licensee must appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program. Deleted: shall Deleted: shall

7-010.02 The Radiation Safety Officer must: Deleted: shall

1. Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations and other deviations from approved radiation safety practice and implement corrective actions as necessary;
2. Establish, collect in one binder or file and implement written policy and procedures for:

   a. Authorizing the purchase of radioactive material;
   b. Receiving and opening packages of radioactive material;
   c. Storing radioactive material;
   d. Keeping an inventory record of radioactive material;
   e. Using radioactive material safely;
   f. Taking emergency action if control of radioactive material is lost;
   g. Performing periodic radiation surveys;
   h. Performing checks and calibrations of survey instruments and other safety equipment;
   i. Disposing of radioactive material;
   j. Training personnel who work in or frequent areas where radioactive material is used or stored; and
   k. Keeping a copy of all records and reports required by the Agency regulations, a copy of Title 180, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

3. Brief management once each year on the radioactive material program;
4. Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.
5. For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; and
6. For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

7-011 RADIATION SAFETY COMMITTEE: Each medical institution licensee must establish a Radiation Safety Committee to oversee the use of radioactive material: Deleted: shall

7-011.01 The Committee must meet the following administrative requirements: Deleted: shall

1. Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate. Deleted: shall
2. The committee must meet at least once each calendar quarter. Deleted: shall

3. To establish a quorum and to conduct business, one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative. Deleted: shall
4. The minutes of each Radiation Safety Committee meeting must include: Deleted: shall

   a. The date of the meeting;
   b. Members present;
   c. Members absent;
   d. Summary of deliberations and discussions;
   e. Recommended actions and the numerical results of all ballots; and
   f. Documentation of any reviews required in 180 NAC 7-009.03 and 180 NAC 7-011.02.

5. The Committee must provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license. Deleted: shall

7-011.02 To oversee the use of licensed material, the Committee must: Deleted: shall

1. Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;
2. Review:

   a. Review, on the basis of safety and with regard to the training and experience standards of this 180 NAC 7-011, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal;
   b. Review, pursuant to 180 NAC 7-007.02, items 1. through 4., on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

3. Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;
4. Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;
5. Review quarterly with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;
6. Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken; and
7. Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

7-012 STATEMENT OF AUTHORITIES AND RESPONSIBILITIES

7-012.01 A licensee must provide sufficient authority and organizational freedom and management prerogative to the Radiation Safety Officer and at a medical institution the Radiation Safety Committee to: Deleted: shall

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

7-012.02 A licensee must establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee. Deleted: shall

7-013 SUPERVISION

7-013.01 A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 180 NAC 7-005.02 must: Deleted: shall

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;
2. Review the supervised individual's use of radioactive material, provide re-instruction as needed and review records kept to reflect this use;
3. Require the authorized user to be immediately available to communicate with the supervised individual; and
4. 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. Deleted: shall

7-013.02 A licensee must require the supervised individual receiving, possessing, using or transferring radioactive material under 180 NAC 7-005 to: Deleted: shall

1. Follow the instructions of the supervising authorized user;
2. Follow the written radiation safety procedures established by the licensee;
3. Follow the procedures established by the Radiation Safety Officer; and
4. Comply with Title 180 and the license conditions with respect to the use of radioactive material.

7-013.03 A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

7-014 RESERVED

7-015 MOBILE NUCLEAR MEDICINE SERVICE ADMINISTRATIVE REQUIREMENTS

7-015.01 The Agency will license mobile nuclear medicine services only in accordance with 180 NAC 7-015 and other applicable requirements of Title 180. An authorized user or an on-site-physician who has met the training and experience requirements of 180 NAC 7-066, needs to be present during administration of radioactive material.

7-015.02 Mobile nuclear medicine service licensees must obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee must retain the letter for three years after the last provision of service.

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7-015.03 If a mobile nuclear medicine service licensee provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in 180 NAC 7-015 while the mobile nuclear medicine service is under the client's direction.

7-015.04 A mobile nuclear medicine service licensee may not order radioactive material to be delivered directly from the manufacturer or the distributor to the client's address of use.

7-016 RESERVED

7-017 NOTIFICATIONS, RECORDS AND REPORTS OF MISADMINISTRATIONS

7-017.01 For any misadministration of radioactive material or radiation:

1. The licensee must notify the Agency by telephone no later than the next day after discovery of the misadministration.

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2. The licensee must submit a written report to the Agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual or the individual's responsible relative or guardian, and if not, why not, and if there was notification, what information was provided. The report must not contain the individual's name or other information that could lead to identification of the individual. To meet the requirements of this 180 NAC 7-017.01, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

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3. The licensee must notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee must not delay appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

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4. If the individual was notified, the licensee must also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

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7-017.02 Each licensee must retain a record of each misadministration for five years. The record must contain the names of all individuals involved in the event, including the prescribing physician, allied health personnel, the individual subject who received the misadministration, and the individual's referring physician, if applicable, the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken, to prevent recurrence.

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7-017.03 Aside from the notification requirement, nothing in this 180 NAC 17-017.03 affects any rights or duties of licensees, and physicians in relation to each other, individuals receiving misadministrations, or the individual's responsible relatives or guardians.

7-018 SUPPLIERS: A licensee must use for medical use only:

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7-018.01 Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 180 NAC 3 and 180 NAC 3-014.10 through 3-014.12 of Title 180 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State;

7-018.02 Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration, the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; or

7-018.03 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 180 NAC 3, or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

SPECIFIC REQUIREMENTS

7-019 POSSESSION, USE, CALIBRATION, AND CHECK OF DOSE CALIBRATORS

7-019.01 A medical use licensee authorized to administer radiopharmaceuticals must possess a dose calibrator and use it to measure the amount of activity administered to each patient and human research subject.

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7-019.02 A licensee must:

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1. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of 180 NAC 7-019.02, the check must be done on a frequently used setting with a sealed source of not less than 370 kBq (10 microcuries) of radium-226 or 1.85 MBq (50 microcuries) of any other photon-emitting radionuclide with a half-life greater than 90 days;

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

3. Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 1.1 MBq (30 microcuries) and the highest dosage that will be administered to a patient or human research subject; and

4. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee must keep a record of this test for the duration of the use of the dose calibrator.

7-019.03 A licensee must mathematically correct dosage readings for any geometry or linearity error that exceeds 10% if the dosage is greater than 370 kBq (10 microcuries) and must repair or replace the dose calibrator if the accuracy or constancy error exceeds 10%.

7-019.04 A licensee must also perform checks and tests required by 180 NAC 7-019.02 following adjustment or repair of the dose calibrator.

7-019.05 A licensee must retain a record of each check and test required by 180 NAC 7-019 for three years. The records required by 180 NAC 7-019.02 must include:

1. For 180 NAC 7-019.02, item 1., the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

2. For 180 NAC 7-019.02, item 2., the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the Radiation Safety Officer;

3. For 180 NAC 7-019.02, item 3., the model and serial number of the dose calibrator, and the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

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4. For 180 NAC 7-019.02, item 4., the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

7-020 CALIBRATION AND CHECK OF SURVEY INSTRUMENTS

7-020.01 A licensee must ensure that the survey instruments used to show compliance with 180 NAC 7-020 have been calibrated before first use, annually, and following repair.

7-020.02 To satisfy the requirements of 180 NAC 7-020.01, the licensee must:

1. Calibrate all required scale readings up to 10 mSv (1000 millirems) per hour with a radiation source;
2. Each scale must be calibrated at 1/3 and 2/3 of the full-scale reading; and
3. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

7-020.03 To satisfy the requirements of 180 NAC 7-020.02, the licensee must consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent, and must conspicuously attach a correction chart or graph to the instrument if the calibration is greater than ± 10% but less than ± 20%. Instruments greater than ± 20% must be repaired or replaced.

7-020.04 A licensee must check each survey instrument for proper operation with the dedicated check source before each day of use. The licensee is not required to keep records of these checks.

7-020.05 The licensee must retain a record of each calibration required in 180 NAC 7-020.01 for three years. The record must include:

1. A description of the calibration procedure; and
2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

7-020.06 To meet the requirements of 180 NAC 7-020.01 through 7-020.03, the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform calibrations of survey instruments. Records of calibrations which contain information required by 180 NAC 7-020.05 must be maintained by the licensee.

7-021 POSSESSION, USE, CALIBRATION, AND CHECK OF INSTRUMENTS TO MEASURE DOSAGE OF ALPHA- OR BETA-EMITTING RADIONUCLIDES

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7-021.01 180 NAC 7-007.21 does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

7-021.02 For other than unit dosages obtained pursuant to 180 NAC 7-201.01, a licensee must possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee must have procedures for use of the instrumentation. The licensee must measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each individual. In addition, the licensee must:

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1. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
2. Check each instrument for constancy and proper operation at the beginning of each day of use.

7-022 MEASUREMENT OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

7-022.01 Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;

7-022.02 Measure, by direct measurement or by combination of measurement and calculations, the activity of each dosage of a alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State Requirements;

7-022.03 Retain a record of the measurements required by 180 NAC 7-022.01 and 7-022.02 for three years. To satisfy this requirement, the record must contain the:

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1. Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
2. Patient's or human research subject's name, and identification number if one has been assigned;
3. Prescribed dosage and activity of the dosage at the time of measurement, or notation that the total activity is less than 1.1 MBq (30 microcuries);
4. Date and time of the administration measurement; and
5. Initials of the individual who made the record.

7-023 AUTHORIZATION FOR CALIBRATION AND REFERENCE SOURCES: Any person authorized by 180 NAC 7-005 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

7-023.01 Sealed sources manufactured and distributed by persons specifically licensed pursuant to 180 NAC 3-014.12 or equivalent provisions of the U.S. Nuclear Regulatory

Commission or Agreement State regulations and that do not exceed 555 MBq (15 millicuries) each;

7-023.02 Any radioactive material authorized by 180 NAC 7-034 or 7-036 with a half-life of 100 days or less in individual amounts not to exceed 555 MBq (15 millicuries);

7-023.03 Any radioactive material authorized by 180 NAC 7-034 or 7-036 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 microcuries) each; and

7-023.04 Technetium-99m in individual amounts not to exceed 1.85 GBq (50 millicuries).

7-024 REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES

7-024.01 A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and must maintain the instructions for the duration of source use in a legible form convenient to users.

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7-024.02 A licensee in possession of a sealed source must assure that:

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1. The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and
2. The source is tested for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission.

7-024.03 To satisfy the leak test requirements of 180 NAC 7-024.02, the licensee must assure that:

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1. Leak tests are capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 Bq (0.001 microcuries) per 24 hours;
2. Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
3. Test samples are taken when the source is in the "off" position.

7-024.04 A licensee must retain leak test records for five years. The records must contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (microcuries), a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer

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7-024.05 If the leak test reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination, the licensee must:

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1. Immediately withdraw the sealed source from use and store it in accordance with the requirements of 180 NAC 4; and
2. File a report with the Agency within five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

7-024.06 A licensee need not perform a leak test on the following sources:

1. Sources containing only radioactive material with a half-life of less than 30 days;
2. Sources containing only radioactive material as a gas;
3. Sources containing 3.7 MBq (100 microcuries) or less of beta or gamma-emitting material or 370 kBq (10 microcuries) or less of alpha-emitting material;
4. Seeds of iridium-192 encased in nylon ribbon; or
5. Sources stored and not being used. The licensee must, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

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7-024.07 A licensee in possession of a sealed source or brachytherapy source must conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee must retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer.

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7-024.08 A licensee in possession of a sealed source or brachytherapy source must survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

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7-024.09 A licensee must retain a record of each survey required in 180 NAC 7-024.08 for three years. The record must include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts (millirems) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

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7-025 SYRINGE SHIELDS

7-025.01 A licensee must keep syringes that contain radioactive material to be administered in a radiation shield.

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7-025.02 A licensee must require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

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7-026 SYRINGE LABELS: Unless utilized immediately, a licensee must conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, and the patient's or human research subject's name.

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7-027 VIAL SHIELDS: A licensee must require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield. Deleted: shall

7-028 VIAL SHIELD LABELS: A licensee must conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation. Deleted: shall

7-029 SURVEYS FOR CONTAMINATION AND AMBIENT RADIATION DOSE RATE

7-029.01 A licensee must survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. Deleted: shall

7-029.02 A licensee must survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored. Deleted: shall

7-029.03 A licensee must conduct the surveys required by 180 NAC 7-029.01 and 7-029.02 so as to be able to measure dose rates as low as 1 μSv (0.1 millirem) per hour. Deleted: shall

7-029.04 A licensee must establish dose rate action levels for the surveys required by 180 NAC 7-029.01 and 7-029.02 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level. Deleted: shall Deleted: shall

7-029.05 A licensee must survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use or administered and where radioactive materials are stored. Deleted: shall

7-029.06 A licensee must conduct the surveys required by 180 NAC 7-029.05 so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm). Deleted: shall

7-029.07 A licensee must establish removable contamination action levels for the surveys required by 180 NAC 7-029.05 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels. Deleted: shall Deleted: shall

7-029.08 A licensee must retain a record of each survey required by 180 NAC 7-029.01, 7-029.02 and 7-029.05 for three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (millirems) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey. Deleted: shall

7-030 RELEASE OF INDIVIDUALS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

7-030.01 The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent 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).[1]

7-030.02 The licensee must provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

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

7-030.03 The licensee must maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

1. Using the retained activity rather than the activity administered,
2. Using an occupancy factor less than 0.25 at 1 meter,
3. Using the biological or effective half-life, or
4. Considering the shielding by tissue.

7-030.04 The licensee must maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

7-031 MOBILE NUCLEAR MEDICINE SERVICE TECHNICAL REQUIREMENTS: A licensee providing mobile nuclear medicine service must:

7-031.01 Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

7-031.02 Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

7-031.03 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

7-031.04 Check survey instruments and dose calibrators as required in 180 NAC 7-019 and 7-020, and check all other transported equipment for proper function before medical use at each address of use;

[1]Regulatory Guide 7.1, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

7-031.05 Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client address of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

7-031.06 Retain a record of each survey required by 180 NAC 7-031.05 for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (millirems) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

7-032 STORAGE OF VOLATILES AND GASES

7-032.01 A licensee must store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container. Deleted: shall

7-032.02 A licensee must store and use a multidose container in a properly functioning fume hood. Deleted: shall

7-033 DECAY-IN-STORAGE

7-033.01 A licensee must hold radioactive material for decay-in-storage before disposal in ordinary trash and is exempt from the waste disposal requirements of 180 NAC 4 if the licensee: Deleted: shall

1. Holds radioactive material for decay a minimum of ten half-lives;
2. Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
3. Removes or obliterates all radiation labels; and
4. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

7-033.02 For radioactive material disposed in accordance with 180 NAC 7-033.01, the licensee must retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal. Deleted: shall

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIALS FOR UPTAKE, DILUTION, OR EXCRETION STUDIES

7-034 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES: A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that is either:

7-034.01 Obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

7-034.02 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-066.02, or an individual under the supervision of either as specified in 180 NAC 7-013.

7-035 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 1.0 µSv (0.1 millirem) per hour to 1000 µSv (100 millirems) per hour. The instrument must be operable and calibrated in accordance with 180 NAC 7-020.

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SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL, GENERATORS, AND REAGENT KITS FOR IMAGING AND LOCALIZATION STUDIES

7-036 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES: A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

7-036.01 Obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent Agreement State requirements; or

7-036.02 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-066.03, or an individual under the supervision of either as specified in 180 NAC 7-013.

7-037 PERMISSIBLE MOLYBDENUM-99 CONCENTRATION

7-037.01 A licensee must not administer to humans a radiopharmaceutical containing more than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m).

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7-037.02 A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators must measure the molybdenum-99 concentration in each eluate or extract.

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7-037.03 A licensee who must measure molybdenum concentration must retain a record of each measurement for three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in MBq (mCi), the measured activity of molybdenum expressed in kBq (µCi), the ratio of the measures

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expressed as kBq (μCi) of molybdenum per MBq (mCi) of technetium, the time and date of the test, and the initials of the individual who performed the test.

7-037.04 A licensee must report immediately to the Agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 180 NAC 7-037.01. Deleted: shall

7-038 CONTROL OF AEROSOLS AND GASES

7-038.01 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. Deleted: shall

7-038.02 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. Deleted: shall

7-038.03 A licensee must only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms. Deleted: shall

7-038.04 Before receiving, using, or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix 004-B of 180 NAC 4. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate. Deleted: shall Deleted: shall

7-038.05 A licensee must post the time calculated in 180 NAC 7-038.04 at the area of use and requires that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed. Deleted: shall

7-038.06 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. Deleted: shall Deleted: shall

7-038.07 A copy of the calculations required in 180 NAC 7-038.04 must be recorded and retained for the duration of the license. Deleted: shall

7-039 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for imaging and localization studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour. If generators (Mo 99m/Tc 99m) are utilized, a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-020. Deleted: shall Deleted: shall

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL FOR THERAPY

7-040 USE OF UNSEALED RADIOACTIVE MATERIAL FOR THERAPEUTIC ADMINISTRATION: A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

1. Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction; or

2. Iodine-131 as iodide for treatment of thyroid carcinoma; or

3. Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases; or

4. Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

5. Gold-198 as colloid for intracavitary treatment of malignant effusions;

6. Strontium-89 as chloride for bone pain;

7. Any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee must comply with the package insert instructions regarding indications and method of administration. Deleted: shall

7-041 SAFETY INSTRUCTION

7-041.01 A licensee must provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-030. Refresher training must be provided at intervals not to exceed one year. Deleted: shall Deleted: shall

7-041.02 To satisfy 180 NAC 7-014.01, the instruction must describe the licensee's procedures for: Deleted: shall

1. Patient or human research subject control;
2. Visitor control;
3. Contamination control;
4. Waste control;
5. Notification of the Radiation Safety Officer or authorized user in case of the patient's or human research subject's death or medical emergency; and
6. 180 NAC 10 training requirements.

7-041.03 A licensee must keep a record of individuals receiving instruction required by 180 NAC 7-041.01, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. The record must be maintained for inspection by the Agency for three years. Deleted: shall Deleted: Such Deleted: shall

7-042 SAFETY PRECAUTIONS

7-042.01 For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-030, a licensee must: Deleted: shall

1. Provide a private room with a private sanitary facility;
2. Post the patient's or the human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;
3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
4. Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 180 NAC 4 and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in µSv (millirems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;
5. Monitor material and items removed from the patient's or the human research subject's room to determine that any contamination 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. Items found to be above background may be cleaned to background levels, decayed to background by storage or disposed of as radioactive waste;
6. Reserved;
7. Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 3.33 Bq (200 dpm) per 100 square centimeters; and
8. Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by 180 NAC 4-052.01 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. Deleted: 0

7-042.02 A licensee must notify the Radiation Safety Officer or the authorized user immediately if the patient or the human research subject dies or has a medical emergency. Deleted: shall

7-043 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for radiopharmaceutical therapy must possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 µSv (0.1 millirem) per hour to 500 µSv (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-020. Deleted: shall Deleted: shall

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS

7-044 USE OF SEALED SOURCES FOR DIAGNOSIS: A licensee must use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions: Deleted: shall

1. Iodine-125, Americium-241, Gadolinium-153 as a sealed source in a device for bone mineral analysis; and
2. Iodine-125 as a sealed source in a portable device for imaging.

7-045 AVAILABILITY OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material as a sealed source for diagnostic purposes must have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instrument must be operable and calibrated in accordance with 180 NAC 7-020. Deleted: shall Deleted: shall

SPECIFIC REQUIREMENTS FOR THE USE OF SOURCES FOR BRACHYTHERAPY

7-046 USE OF SOURCES FOR BRACHYTHERAPY: A licensee must use the following sources in accordance with the manufacturer's radiation safety and handling instructions: Deleted: shall

1. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
2. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
3. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
4. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;
5. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
6. Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;
7. Radon-222 as seeds for interstitial treatment of cancer;
8. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and
9. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

7-047 SAFETY INSTRUCTION

7-047.01 The licensee must provide oral and written radiation safety instruction to all personnel caring for a patient or the human research subject receiving implant therapy. Refresher training must be provided at intervals not to exceed one year. Deleted: shall Deleted: shall

7-047.02 To satisfy 180 NAC 7-047.01, the instruction must describe: Deleted: shall

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions in case of a dislodged source;

3. Procedures for patient or human research subject control;
4. Procedures for visitor control;
5. Procedures for notification of the Radiation Safety Officer or authorized user if the patient or the human research subject dies or has a medical emergency; and
6. 180 NAC 10 training requirements.

7-047.03 A licensee must maintain for three years a record of individuals receiving instruction required by 180 NAC 7-047.01 and 7-047.02, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Deleted: shall

7-048 SAFETY PRECAUTIONS

7-048.01 For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to 180 NAC 7-030, a licensee must: Deleted: shall

1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy;
2. 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. In addition, the posted sign must indicate that pregnant women, or women who suspect that they are pregnant, must contact the attendant staff for additional safety instructions or precautions. The bed, cubicle, or room of the hospital brachytherapy patient or human research subject must be marked with a sign indicating the presence of brachytherapy sources. This sign must incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. Deleted: shall Deleted: shall Deleted: shall Deleted: shall
3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with approval of the authorized user after consultation with the Radiation Safety Officer;
4. Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 180 NAC 4 and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in μSv (millirems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

7-048.02 A licensee must notify the Radiation Safety Officer or authorized user immediately if the patient or the human research subject dies or has a medical emergency. Deleted: shall

7-048.03 The following information must be included in the patient's or human research subject's chart: Deleted: shall

1. The radionuclide administered, number of sources, activity in GBq or mCi and time and date of administration;
2. The exposure rate at 1 meter, the time the determination was made, and name of the individual who made the determination;

3. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 180 NAC 4-006, and;
4. The radiation symbol.

7-049 BRACHYTHERAPY SOURCES INVENTORY

7-049.01 Promptly after removing them from a patient or a human research subject, a licensee must return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned. Deleted: shall

7-049.02 A licensee must make a record of brachytherapy source utilization which includes: Deleted: shall

1. The names of the individuals permitted to handle the sources;
2. The number and activity of sources removed from storage, the room number of use and the patient's or the human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and
3. The number and activity of sources returned to storage, the room number of use and patient's or the human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

7-049.03 Immediately after implanting sources in a patient or a human research subject, the licensee must make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee must make a record of each survey. Deleted: shall Deleted: shall

7-049.04 A licensee must maintain the records required in 180 NAC 7-049.02 and 7-049.03C for three years. Deleted: shall

7-050 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS TREATED WITH TEMPORARY IMPLANTS

7-050.01 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must perform a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee must not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed. Deleted: shall Deleted: shall

7-050.02 A licensee must maintain for three years a record of patient or human research subject surveys which demonstrate compliance with 180 NAC 7-050.01. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as μSv (millirems) per hour and measured within one meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey. Deleted: shall Deleted: shall

7-051 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for implant therapy must possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 007.20.

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SPECIFIC REQUIREMENTS FOR THE USE OF A SEALED SOURCE IN TELETHERAPY

7-052 USE OF A SEALED SOURCE IN A TELETHERAPY UNIT: A licensee must use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

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7-053 MAINTENANCE AND REPAIR RESTRICTIONS: Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair must install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

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7-054 AMENDMENTS: In addition to the requirements specified in 180 NAC 7-007, a licensee must apply for and receive a license amendment before:

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1. Making any change in the treatment room shielding;
2. Making any change in the location of the teletherapy unit within the treatment room;
3. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
4. Relocating the teletherapy unit; or
5. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

7-055 SAFETY INSTRUCTION

7-055.01 A licensee must conspicuously post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

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1. The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;
2. The procedure to be followed if the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and
3. The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

7-055.02 A licensee must provide instruction in the topics identified in 180 NAC 7-055.01 to all individuals who operate a teletherapy unit and must provide appropriate refresher training to individuals at intervals not to exceed one year. Deleted: shall Deleted: shall

7-055.03 A licensee must maintain for three years a record of individuals receiving instruction required by 180 NAC 7-055.02, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Deleted: shall

7-056 SAFETY PRECAUTIONS

7-056.01 A licensee must control access to the teletherapy room by a door at each entrance. Deleted: shall

7-056.02 A licensee must equip each entrance to the teletherapy room with an electrical interlock system that must: Deleted: shall Deleted: shall

1. Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;
2. Turn the primary beam of radiation off immediately when an entrance door is opened; and
3. Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

7-056.03 A licensee must equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light. Deleted: shall

7-056.04 A licensee must have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status. Deleted: shall

1. Each radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room. Deleted: shall
2. Each radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system. Deleted: shall
3. A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects. Deleted: shall
4. A licensee must maintain a record of the check required by 180 NAC 7-056.04, item 3. for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check. Deleted: shall Deleted: shall
5. If a radiation monitor is inoperable, the licensee must require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The Deleted: shall

instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee must keep a record as described in 180 NAC 7-056.04, item 4.

6. A licensee must promptly repair or replace the radiation monitor if it is inoperable.

7-056.05 A licensee must construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

7-057 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material in a teletherapy unit must possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 1 µSv (0.1 millirem) per hour to 500 µSv (50 millirems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-020.

7-058 DOSIMETRY EQUIPMENT

7-058.01 A licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

1. The system must have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

2. The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee must not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee must use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee must use a teletherapy unit with a cesium-137 source.

7-058.02 The licensee must have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 180 NAC 7-058.01. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system must be the same system used to meet the requirement in 180 NAC 7-058.01.

7-058.03 The licensee must maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 180 NAC 7-058.01 and 7-058.02, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM.

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7-059 FULL CALIBRATION MEASUREMENTS

7-059.01 A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:

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

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

3. At intervals not exceeding one year.

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7-059.02 To satisfy the requirement of 180 NAC 7-059.01, full calibration measurements must include determination of:

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

Deleted: percent

7-059.03 A licensee must use the dosimetry system described in 180 NAC 7-058.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required by 7-059.02, item 1. may then be made using a dosimetry system that indicates relative dose rates.

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7-059.04 A licensee must make full calibration measurements required by 180 NAC 7-059.01 in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p.213. Both of these documents are incorporated herein by reference and available for viewing at the Department of Health and Human Services Regulation and Licensure, Public Health Assurance 301 Centennial Mall South, 3rd floor, Lincoln, Nebraska 68509-5007. Deleted: shall

7-059.05 A licensee must correct mathematically the outputs determined in 180 NAC 7-059.02, item 1. for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137. Deleted: shall

7-059.06 Full calibration measurements required by 180 NAC 7-059.01 and physical decay corrections required by 180 NAC 7-059.05 must be performed by a teletherapy physicist. Deleted: shall

7-059.07 A licensee must maintain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer, linearity and constancy, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist. Deleted: shall Deleted: shall

7-060 PERIODIC SPOT-CHECKS

7-060.01 A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit at intervals not to exceed one month. Deleted: shall

7-060.02 To satisfy the requirement of 180 NAC 7-060.01, spot-checks must include determination of: Deleted: shall

1. Timer constancy and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions; and
6. The difference between the measurement made in 180 NAC 7-060.02, item 5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

7-060.03 A licensee must use the dosimetry system described in 180 NAC 7-058 to make the spot-check required in 180 NAC 7-060.02, item 5. Deleted: shall

7-060.04 A licensee must perform spot checks required by 180 NAC 7-060.01 through 7-060.03 in accordance with procedures established by the radiological physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements. Deleted: shall

7-060.05 A licensee must have the teletherapy physicist review the results of each output spot-check within 15 days. The teletherapy physicist must promptly notify the licensee in writing of the results of each output spot check. The licensee must keep a copy of each written notification for three years. Deleted: shall Deleted: shall Deleted: shall

7-060.06 A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility at intervals not to exceed one month. Deleted: shall

7-060.07 To satisfy the requirement of 180 NAC 7-060.06, safety spot-checks must assure proper operation of: Deleted: shall

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

7-060.08 A licensee must arrange for prompt repair of any system identified in 180 NAC 7-060.06 and 7-060.07 that is not operating properly, and must not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired. Deleted: shall Deleted: shall

7-060.09 A licensee must maintain a record of each spot-check required by 180 NAC 7-060.01, 7-060.02, 7-060.03, 7-060.06 and 7-060.07 for three years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check. Deleted: shall Deleted: shall

7-061 RADIATION SURVEYS FOR TELETHERAPY FACILITIES

7-061.01 Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 180 NAC 7-054, item 1 through item 4, the licensee must perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 180 NAC 7-020 to verify that: Deleted: shall

1. The maximum and average radiation levels at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 μSv (10 millirems) per hour and 20 μSv (2 millirems) per hour, respectively; and

2. With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

   a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 180 NAC 4-006 and
   b. Radiation levels in unrestricted areas do not exceed the limits specified in 180 NAC 4-014.

7-061.02 If the results of the surveys required in 180 NAC 7-061.01 indicate any radiation levels in excess of the respective limit specified in that part, the licensee must lock the control in the off position and not use the unit: Deleted: shall

1. Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or
2. Until the licensee has received a specific exemption pursuant to 180 NAC 4-013 from the Agency.
3. A licensee must maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in μSv (millirems) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer. Deleted: shall Deleted: shall

7-062 SAFETY SPOT CHECKS FOR TELETHERAPY FACILITIES

7-062.01 A licensee must promptly check all systems listed in 180 NAC 7-060.06 and 7-060.07 for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 180 NAC 7-054, item 1 through item 4. Deleted: shall

7-062.02 If the results of the safety spot checks required in 180 NAC 7-062.01 indicate the malfunction of any system specified in 180 NAC 7-060.06 and 7-060.07, the licensee must Deleted: shall

lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7-062.03 A licensee must maintain a record of the safety spot checks following installation of a source for three years. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the Radiation Safety Officer.

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7-063 MODIFICATION OF TELETHERAPHY UNIT OR ROOM BEFORE BEGINNING A TREATMENT PROGRAM: If the survey required by 180 NAC 7-061 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 180 NAC 4-014, before beginning the treatment program the licensee must:

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7-063.01 Either equip the unit with stops or add additional radiation shielding to ensure compliance with 180 NAC 4-014.03;

7-063.02 Perform the survey required by 180 NAC 7-061 again; and

7-063.03 Include in the report required by 180 NAC 7-064 the results of the initial survey, a description of the modification made to comply with 180 NAC 7-063.01, and the results of the second survey; or

7-063.04 Request and receive a license amendment under 180 NAC 4-014.03 that authorized radiation levels in unrestricted areas greater than those permitted by 180 NAC 4-014.01, item 2.

7-064 REPORTS OF TELETHERAPY SURVEYS, CHECKS, TESTS, AND MEASUREMENTS: A licensee must furnish a copy of the records required in 180 NAC 7-061 through 7-063 and the output from the teletherapy source expressed in roentgens, coulombs/kilogram, rads, or grays per hour at one meter from the source as determined during the full calibration required in 180 NAC 7-059 to the Agency within 30 days following completion of the action that initiated the record requirement.

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7-065 FIVE-YEAR INSPECTION

7-065.01 A licensee must have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

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7-065.02 This inspection and servicing must only be performed by persons specifically licensed to do so by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State.

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7-065.03 A licensee must maintain a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

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SPECIFIC REQUIREMENTS FOR TRAINING

7-066 TRAINING AND EXPERIENCE: The training and experience requirements for individuals using radioactive materials in 180 NAC 7-066 are as follows:

7-066.01 Radiation Safety Officer: The licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who: Deleted: shall

1. Is certified by:

   a. American Board of Health Physics in Comprehensive Health Physics;
   b. American Board of Radiology;
   c. American Board of Nuclear Medicine;
   d. American Board of Science in Nuclear Medicine;
   e. Board of Pharmaceutical Specialties in Nuclear Pharmacy;
   f. American Board of Medical Physics in radiation oncology physics;
   g. Royal College of Physicians and Surgeons of Canada in nuclear medicine;
   h. American Osteopathic Board of Radiology; or
   i. American Osteopathic Board of Nuclear Medicine; or

2. Has had classroom and laboratory training and experience as follows:

   a. Two-Hundred hours of classroom and laboratory training that includes: Deleted: (200)

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

   b. One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory Commission or an Agreement State license that authorizes the medical use of radioactive material; or

3. Be an authorized user identified on the licensee's license.

7-066.02 Training for Uptake, Dilution, and Excretion Studies. The licensee must require the authorized user of a radiopharmaceutical in 180 NAC 7-034 to be a physician who: Deleted: shall

1. Is certified in:

   a. Nuclear medicine by the American Board of Nuclear Medicine; or
   b. Diagnostic radiology by the American Board of Radiology; or

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
e. American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

a. Forty hours of classroom and laboratory training that includes: Deleted: (40)

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

b. Twenty hours of clinical experience under the supervision of an authorized user and includes: Deleted: (20)

(1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
(2) Selecting an appropriate radiopharmaceutical and measuring the dosages;
(3) Administering dosages to patients or human research subjects using syringe radiation shields;
(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and
(5) Patient or human research subject follow-up; or

c. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all topics identified in 180 NAC 7-066.02, item 2.b.

7-066.03 Training for Imaging and Localization Studies. The licensee must require the authorized user of a radiopharmaceutical, generator, or reagent kit in this group to be a physician who: Deleted: shall

1. Is certified in:

a. Nuclear medicine by the American Board of Nuclear Medicine; or
b. Diagnostic radiology by the American Board of Radiology; or
c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
e. American Osteopathic Board of Nuclear Medicine; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

a. Two-Hundred hours of classroom and laboratory training that includes: Deleted: (200)

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Biological effects of radiation; and
(5) Radiopharmaceutical chemistry; and

b. Five-Hundred hours of work experience under the supervision of an authorized user that includes: Deleted: (500)

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(2) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
(3) Calculating and safely preparing patient or human research subject dosages;
(4) Using administrative controls to prevent the misadministration of radioactive material;
(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
(6) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

c. Five-Hundred hours of clinical experience under the supervision of an authorized user that includes: Deleted: (500)

(1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
(2) Selecting an appropriate radiopharmaceutical and measuring the dosages;
(3) Administering dosages to patients or human research subjects using syringe radiation shields;
(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and
(5) Patient or human research subject follow-up; or

3. Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 180 NAC 7-066.03, item 2.

NOTE: The requirements specified in 180 NAC 7-066.03. item 2.a., 7-066.03, item 2.b., and 7-066.03, item 2.c. may be satisfied concurrently if all three are included in the training program. Each physician named in Item 4 of Form NRH-5A (Medical/Teletherapy) must complete a separate Form NRH-5A (Medical/Teletherapy) Supplement A (Training and Experience, Authorized User or Radiation Safety Officer) and Form NRH-5A (Medical/Teletherapy) Supplement B (Preceptor Statement).

7-066.04 Training for Therapeutic Use of Unsealed Radioactive Material: The licensee must require the authorized user of unsealed radioactive material in 180 NAC 7-040 to be a physician who: Deleted: shall

1. Is certified by:

   a. The American Board of Nuclear Medicine; or
   b. The American Board of Radiology in radiology, therapeutic radiology or radiation oncology; or
   c. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
   d. The American Osteopathic Board of Radiology after the effective date of Title 180; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic unsealed radioactive materials, and supervised clinical experience as follows:

   a. Training in basic radioisotope handling techniques of eighty hours, including Deleted: (80 Deleted:)

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

   b. Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

      (1) Use of Iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction ten individuals; and Deleted: 10 (Deleted:)

(2) Use of Iodine-l3l for treatment of thyroid carcinoma in three individuals.
(3) Use of Phosphorous-32 for treatment of polycythemia vera, leukemia and /or bone metastases in three individuals.
(4) Use of Colloidal Phosphorous-32 for intracavitary treatment in three individuals.
(5) Use of Colloidal Gold-198 for intracavitary treatment in three individuals.
(6) Use of Strontium-89 for intracavitary treatment in three individuals.
(7) Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA), or an approved "Product License Approval" (PLA).

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7-066.05 Training For On-Site Physician: The on-site physician must have a minimum of forty hours of formal training in basic radiological handling techniques.

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7-066.06 Training for Use of Brachytherapy Sources: The licensee must require the authorized user of a brachytherapy source listed in 180 NAC 7-046 for therapy to be a physician who is:

Deleted: shall

1. Certified in:

   a. Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;
   b. Radiation oncology by the American Osteopathic Board of Radiology;
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology;" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

2. Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

   a. Two-Hundred hours of classroom and laboratory training that includes:

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

   b. Five-Hundred hours of work experience under the supervision of an authorized user at a medical institution that includes:

Deleted: (200)

Deleted: (500)

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

c. Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(1) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
(2) Selecting the proper brachytherapy sources and dose and method of administration;
(3) Calculating the dose; and
(4) Post-administration follow-up and review of case histories in collaboration with the authorized user.

7-066.07 Training for Ophthalmic Use of Strontium-90: The licensee must require the authorized user of only Strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of Strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

Deleted: shall

1. Twenty-Four hours of classroom and laboratory training that includes:

Deleted: (24)

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

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Strontium-90 for the ophthalmic treatment of five individuals that includes:

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

7-066.08 Training for Use of Sealed Sources for Diagnosis: The licensee must require the authorized user of a sealed source in a device listed in 180 NAC 7-044 to be a physician, dentist, or podiatrist who: Deleted: shall

1. Is certified in:

   a. Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;
   b. Nuclear medicine by the American Board of Nuclear Medicine; or
   c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
   d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. Has had eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes: Deleted: 8

   a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
   b. Radiation biology;
   c. Radiation protection; and
   d. Training in the use of the device for the uses requested.

7-066.09 Training for Teletherapy: The licensee must require the authorized user of a sealed source listed in 180 NAC 7-052 in a teletherapy unit to be: Deleted: shall

1. A physician who is authorized to practice medicine in Nebraska.
2. Certified in:

   a. Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

3. Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

   a. Two-Hundred hours of classroom and laboratory training that includes: Deleted: (200)

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

b. Five-Hundred hours of work experience under the supervision of an authorized user at a medical institution that includes:

(1) Review of the full calibration measurements and periodic spot checks;
(2) Preparing treatment plans and calculating treatment times;
(3) Using administrative controls to prevent misadministrations;
(4) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
(5) Checking and using survey meters; and

Deleted: (500)

c. Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(1) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
(2) Selecting the proper dose and how it is to be administered;
(3) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by individuals' reaction to radiation; and
(4) Post-administration follow-up and review of case histories.

7-066.10 Training for Teletherapy Physicist: The licensee must require the teletherapy physicist to be an individual who:

Deleted: shall

1. Is certified by the American Board of Radiology in:

a. Therapeutic radiological physics;
b. Roentgen ray and gamma ray physics;
c. X-ray and radium physics; or
d. Radiological Physics; or

2. Is certified by the American Board of Medical Physics in radiation oncology physics; or
3. Holds a master's or doctor's degree in physics, biophysics, radiological physics or health physics, and has completed one year full time training in therapeutic radiological physics and a an additional year of full time experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in 180 NAC 7-024, 7-059, 7-060, and 7-061.

7-066.11 Physician Training in a Three Month Program: A physician who, before September 17, 1997, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of 180 NAC 7-066.02 or 7-066.03.

Deleted: the effective date of Title 180

7-066.12 Recentness of Training: The training and experience specified in this subpart must have been obtained within seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Deleted: 7

7-066.13 Training And Experience Requirements For Nuclear Medicine Technologists:

1. The licensee must require that a technologist who uses any radiopharmaceutical, generator, or reagent kit in 180 NAC 7-036 be an individual who:

Deleted: shall

   a. Is certified in nuclear medicine by the:

      (1) American Registry of Radiologic Technologists; or
      (2) Nuclear Medicine Technology Certification Board; or

   b. Has completed an integrated program of full-time training and experience that includes classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised handling experience, and supervised clinical experience as follows:

      (1) Two-hundred hours of classroom and laboratory training that include:

Deleted: 200

         (a) Radiation physics and instrumentation;
         (b) Radiation protection policy, management, procedures, and regulations;
         (c) Mathematics of radiation and radioactivity;
         (d) Radiopharmaceutical chemistry;
         (e) Imaging technology; and
         (f) Radiation biology.

      (2) Supervised handling experience under the supervision of an authorized user or practicing technologist that includes:

         (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
         (b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
         (c) Calculating and safely preparing stock radiopharmaceuticals and individual dosages.
         (d) Using administrative controls to prevent the misadministration of radioactive material;
         (e) Containing spilled radioactive material and decontaminating; and
         (f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and assaying radiopharmaceuticals to determine the portion of radioactivity bound to the radiopharmaceutical.

(3) Supervised clinical experience under the supervision of an authorized user that includes:

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

7-066.14 Training And Experience Requirements For Radiation Therapists:

1. The licensee must require that a radiation therapist who uses any source of radiation for therapy listed in 180 NAC 6 , 7 or 9 be an individual who: Deleted: shall

a. Is certified in radiation therapy technology by the American Registry of Radiologic Technologists; or
b. Has completed an integrated program of full-time training and experience that includes classroom and laboratory training applicable to the use of a source of radiation, supervised work experience, and supervised clinical experience as follow:
(1) Two hundred hours of classroom and laboratory training that include: Deleted: 200

(a) Radiation physics and instrumentation;
(b) Radiation protection policy, management, procedures, and regulations;
(c) Mathematics of radiation and radioactivity; and
(d) Radiation biology;

(2) Supervised work experience under the supervision of an authorized user or practicing radiation therapist that includes;

(a) Review of the full calibration measurements and periodic spot checks as appropriate;
(b) Preparing treatment plans for prescriptions and calculating treatment times;
(c) Using administrative controls to prevent misadministrations;
(d) Implementing emergency procedures to be followed in the event of the abnormal operation of equipment; and
(e) Checking and using survey meters; and

(3) Supervised clinical experience under the supervision of an authorized user or a practicing radiation therapist, that includes:

(a) Reviewing the case histories of individuals to determine their suitability for treatment, and any limitations or contraindications;
(b) Selecting the proper doses and how it is to be administered;

(c) Reviewing calculations of radiation source doses for accuracy and completeness; and monitoring patients or human research subjects reaction to radiation, and bringing discrepancies to the authorized user's attention.
(d) Application of radiation to individuals, including the use of beam modifying devices, based on the instructions in the individual's chart; and
(e) Making and reviewing records of the medical use of radiation.

7-066.15 Training for an Authorized Nuclear Pharmacist: The licensee must require the authorized nuclear pharmacist to be a pharmacist who:

Deleted: shall

1. Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
2. Has completed 700 hours in structured educational program consisting of both:

Deleted: seven-hundred (
Deleted:)

a. Didactic training in the following areas:

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

b. Supervised experience in a nuclear pharmacy involving the following:

(1) Shipping, receiving, and performing related radiation surveys;
(2) Using and performing checks for proper operation of dose calibrators, and survey meters, and if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
(3) Calculating, assaying and safely preparing dosages for individuals;
(4) Using administrative controls to avoid mistakes in the administration of radioactive material;
(5) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

3. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

7.066.16 Training for Experienced Nuclear Pharmacists: A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 180 NAC 7-066.15, item 2. before the effective date of, and who is working in a nuclear pharmacy as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (180 NAC 7-066.15, item 3.) and recentness of training (180 NAC 7-066.12) to qualify as an authorized nuclear pharmacist.

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - Medical or Teletherapy

INSTRUCTIONS - (Use additional sheets where necessary.)
Medical Application - Complete Items 1. through 26.
Teletherapy Application - Complete Items 1. through 26, as applicable and Supplement C.
Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

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

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

eMail Address:

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

(1) Permanent Address: _____

_____

City, State Zip+4: _____

(2) Temporary Job Sites Throughout Nebraska? ❒ Yes ❒ No

2. Person to Contact Regarding this Application

_____

Telephone #: _____

3. This is an application for:

❒ New License

❒ Amendment to License No. _____

❒ Renewal of License No. _____

4. Individual User(s)
(Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials. Complete NRH-5A, Supplement A and B for each individual listed.)

First Name + Middle Initial	Last Name	Title

5. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer.

_____

Telephone #: _____

Attach documentation of his/her training and experience as in NRH-5A, Supplement A.)

Agency Use Only

Date Received Stamp

6. Radioactive Material Data

6. Radioactive Material for Medical Use

Radioactive Material Listed In:	Items Desired (X)	Maximum Possession Limits (In millicuries)
Title 180 NAC 3-008.09 for Invitro Studies		
Title 180 NAC 7-034.01		
Title 180 NAC 7-036		
Title 180 NAC 7-040		
Title 180 NAC 7-044		
Title 180 NAC 7-046		
Additional Items		
Xenon-133 as gas or gas in saline for blood flow studies and pulmonary function studies		
Technetium-99m aerosolized DTPA for pulmonary function studies		
High dose rate remote afterloading brachytherapy device		

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

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

Instructions for Items 7. Through 23.

For Items 7. through 23., check the appropriate box(es) and submit a detailed description of all the requested information. Begin each Item on a separate sheet, identifying the Item number and the date of the application in the lower right hand corner of each page.
If you indicate that you will follow an Appendix to the *Guide for Preparation of Applications for Medical Programs 7.0,* do not submit the pages, but specify the revision number and date of the *Guide.*
The Most current *Guide* is: Revision:_____ Date:_____

7. Radiation Safety Committee
- ☐ Names and Specialities attached; **AND**
- ☐ Duties as in Appendix B; **OR** Equivalent Duties attached

8. Training and Experience
- ☐ Supplements A and B attached for each individual user; **AND**
- ☐ Supplement A attached for RSO

9. Instrumentation
- ☐ Appendix C Form attached; **OR**
- ☐ List by Name and Model Number

10. Calibration of Instruments

a. Survey Instruments
- ☐ Appendix D Procedures followed; **OR**
- ☐ Equivalent Procedures attached

AND

b. Dose Calibrator
- ☐ Appendix D Procedures followed; **OR**
- ☐ Equivalent Procedures attached

11. Facilities and Equipment
- ☐ Description or diagram attached; **OR**
- ☐ See Supplements C - Teletherapy Requirements

12. Personnel Training Program
- ☐ Description of training attached

13. Procedures for Ordering and Receiving Radioactive Materials
- ☐ Detailed Information Attached

14. Procedures for Safely Opening Packages Containing Radioactive Materials
- ☐ Appendix F Procedures followed; **OR**
- ☐ Equivalent Procedures attached

15. General Rules for the safe use of Radioactive Material
- ☐ Appendix G Procedures followed; **OR**
- ☐ Equivalent Procedures attached

16. Emergency Procedures
- ☐ Appendix H Procedures followed; **OR**
- ☐ Equivalent Procedures attached

17. Area Survey Procedures
- ☐ Appendix I Procedures followed; **OR**
- ☐ Equivalent Procedures attached

18. Waste Disposal
- ☐ Appendix J Form attached; **OR**
- ☐ Equivalent Information attached

19. Therapeutic Use of Radiopharmaceuticals
- ☐ Appendix K Procedures followed; **OR**
- ☐ Equivalent Procedures attached

20. Therapeutic Use of Sealed Sources
- ☐ Detailed Information attached; **AND**
  - ☐ Appendix L Procedures followed; **OR**
  - ☐ Equivalent Procedures attached

21. Procedures and Precautions for use of Radioactive Gases (e.g., Xenon-133)
- ☐ Detailed Information attached

22. Procedures and Precautions for Use of Radioactive Material in Animals
- ☐ Detailed Information attached

23. Procedures and Precautions for Use of Radioactive Material Specified in Item 6.b.
- ☐ Detailed Information attached

24. Personnel Monitoring Devices

(Check and/or complete as appropriate)

Type	Supplier/Service Company	Exchange Frequency
24.a. Whole Body ☐ Film Badge ☐ TLD ☐ DOSL ☐ Other: (Specify)		☐ Monthly ☐ Quarterly ☐ Other: (Specify)
24.b. Finger ☐ Film Badge ☐ TLD ☐ Other: (Specify)		☐ Monthly ☐ Quarterly ☐ Other: (Specify)
24.c. Wrist ☐ Film Badge ☐ TLD ☐ Other: (Specify)		☐ Monthly ☐ Quarterly ☐ Other: (Specify)
24d. Other (Specify)		

25. Private Practice Applicants Only

25.a. Hospital Agreeing to accept patients containing Radioactive Material:

Name:_____

Mailing Address:_____

_____

City, State Zip+4:_____

25.b. Attach a copy of the agreement letter signed by the hospital administrator.

25.c. When requesting Therapy Procedures, attach a copy of Radiation Safety Precautions to be taken and list available radiation detection instruments.

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

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

_____
Applicant Name From Item 1.a.

By: _____ *Date:* _____
Signature

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

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT A

Training and Experience
Authorized User or Radiation Safety Officer (RSO)

1. Name of Individual	2. Physician who is licensed to dispense drugs in the practice of medicine in Nebraska?
☐ Authorized User ☐ Radiation Safety Officer	☐ YES ☐ NO

3. Certification

3.a. Specialty Board	3.b. Category	3.c. Month and Year Certified

4. Training Received in Basic Radioisotope Handling Techniques

	Location and Dates of Training	Clock Hours in Lecture or Laboratory	Clock Hours of Supervised Laboratory Experience
4.a. Radiation Physics and Instrumentation			
4.b. Radiation Protection			
4.c. Mathematics Pertaining to the Use and Measurement of			
4.d. Biological Effects of Radiation			
4.e. Radiopharmaceutical Chemistry			

5. Experience with Radiation
(Actual Use of Radioisotopes or Equivalent Experience)

Isotope	Maximum Activity	Where Experience Was Gained	Months/Years	Type of Use

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT B
Preceptor Statement

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. Full Name and Street Address of Applicant Physician

Full Name:	
Address:	
City, State Zip+4	

2. Clinical Training and Experience with Radiation

(Actual Use of Radioisotopes)

Isotope	Conditions Diagnosed or Treated	Number of Cases Involving Personal Participation[1]	Comments[2]
I-125 or I-131	Diagnosis of Thyroid Function		
	Determination of Blood and Blood Plasma Volume		
	Liver Function Studies		
	Fat Absorption Studies		
	Kidney Function Studies		
	In vitro Studies		
Other			
I-125	Detection of Thrombosis		
I-131	Thyroid Imaging		
P-32	Eye Tumor Localization		
Se-75	Pancreas Imaging		
Yb-169	Cisternography		
Xe-133	Blood Flow Studies and Pulmonary Function Studies		
Other			
Tc-99m	Brain Imaging		
	Cardiac Imaging		
	Thyroid Imaging		
	Salivary Gland Imaging		
	Blood Pool Imaging		
	Placenta Localization		
	Liver and Spleen Imaging		

1. Full Name and Street Address of Applicant Physician			
	Lung Imaging		
	Bone Imaging		

2. Clinical Training and Experience with Radiation

(Actual Use of Radioisotopes)

Other			
P-32 (Soluble)	Treatment of Polycythemia Vera, Leukemia, and Bone Metastases		
P-32 (Colloidal)	Intracavitary Treatment		
I-131	Diagnosis of Thyroid Function		
	Treatment of Hyperthyroidism		
Au-198	Intracavitary Treatment		
Co-60 or Cs-137	Interstitial Treatment		
	Intracavitary Treatment		
I-125 or Ir-192	Interstitial Treatment		
Ra-226	Intracavitary Treatment		
	Interstitial Treatment		
	Superficial Treatment		
Co-60 or Cs-137	Teletherapy Treatment		
Sr-90	Treatment of Eye Disease		
	Radiopharmaceutical Preparation		
Mo-99/Tc-99m	Generator		
Sn-113/In-113m	Generator		
Tc-99m	Reagent Kits		
X-Ray and Accelerator Therapy	Courses of Therapy Treatment		
Other			

[1] Key to column
Personal Participation should consist of:
1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements, and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

[2] Additional information or comments may be submitted in duplicate on separate sheets.
plicate on separate sheets.

3. Dates and Total Number of Hours Received in Clinical Radioisotope Training
(Submit in duplicate on separate sheets)

4. Training and Experience Obtained Under the Supervision of:

Supervisor's Name:

Institution Name:

Address

City, State Zip+4

Radioactive material License Number(s):

5. Preceptor's Verification

Preceptor's Name:_____
(Type or Print)

Preceptor's Name:_____
(Type or Print)

_____
(Date)

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT C

Requirements Specific to Teletherapy

1. **Facilities and Equipment**
   - ☐ Description and drawing of facilities attached; **AND**
   - ☐ Description of patient viewing and communicating systems attached; **AND**
   - ☐ Description of area safeguards attached

2. **Beam Stops**
   - ☐ Description of stops used to restrict beam orientation attached

3. **Shielding Evaluation**
   - ☐ Evaluation of proposed shielding attached

4. **Operating and Emergency Procedures**
   - ☐ Description of operating procedures attached; **AND**
   - ☐ Copy of emergency procedures attached

5. **Instruction of Personnel**
   - ☐ Training program and schedule in Appendix A followed; **OR**
   - ☐ Description of instruction program for employees attached

6. **Leak Tests of Sealed Sources**
   - ☐ Description of leak test procedures attached

7. **Teletherapy Physicist (Use only if individual fails to meet 180 NAC 7-066.10 requirements)**
   - ☐ Statement of qualifications of the physicist who will perform teletherapy calibrations attached.

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