CHAPTER 33-10-05
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Section	
33-10-05-01	Purpose
33-10-05-02	Scope
33-10-05-03	Definitions
33-10-05-03.1	Exemptions
33-10-05-04	Equipment Control
33-10-05-05	Personal Radiation Safety Requirements for Radiographic Personnel
33-10-05-06	Precautionary Procedures in Radiographic Operations

33-10-05-01. Purpose. This chapter establishes radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, the other applicable requirements of this article.

History: Amended effective June 1, 1986; June 1, 1992.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-02. Scope. This chapter applies to all licensees or registrants who use sources of radiation for industrial radiography. Except for those requirements of this chapter clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this chapter. This rule does not apply to medical uses of radioactive material.

History: Amended effective June 1, 1992.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-03. Definitions. As used in this chapter, the following definitions apply:

1. "Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new

procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

2. "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, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head).

~~1~~3. "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meets the ~~conditions~~ dose limits for individual members of the public as specified in subsection 1 of section 33-10-04.1-07.

~~2~~4. "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. 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 ionizing 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. An 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.

~~3~~5. "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.

6. "Certifying entity" means an independent certifying organization meeting the requirements in appendix B of this chapter or another agreement state meeting the requirements in appendix B, parts II and III of this chapter.

~~4~~7. "Collimator" means a ~~device used to limit the size, shape, and direction of the primary radiation beam~~ 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.

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

9. "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

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

11. "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

12. "Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

13. "Guide tube (projection sheath)" means a flexible or rigid tube (i.e., "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.

14. "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.

15. "Independent certifying organization" means an independent organization that meets all of the criteria of appendix B of this chapter.

~~5~~16. "Industrial radiography" means the examination of the ~~macroscopic~~ structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

17. "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

~~6~~18. "Lixiscope" means a portable light-intensified imaging device using a sealed source.

19. "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

~~7~~20. "Permanent radiographic installation" means ~~a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed~~ an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

~~8~~21. "Personal supervision" means guidance and instruction provided to a radiographer's ~~trainee~~ assistant by a qualified radiographer ~~instructor~~ who is physically present at the site, in visual contact with the ~~trainee~~ assistant while the ~~trainee~~

assistant is using sources of radiation and associated equipment, and in such proximity that immediate assistance can be given if required.

22. "Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

23. "Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of subsection 2 of section 33-10-05-05.

~~9~~24. "Radiographer" means any individual who performs or personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of this article and all license (or certificate of registration) conditions.

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

26. "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

~~10. "Radiographer instructor" means any radiographer who has been authorized by the department to provide on-the-job training to radiographer trainees in accordance with subdivision e of subsection 5 of section 33-10-05-06.~~

~~11. "Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of their instruction.~~

~~12~~28. "Radiographic exposure device" (also called a camera, or a 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.

29. "Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include

surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

~~13~~30. "Radiographic personnel" means any radiographer, ~~radiographer instructor,~~ or radiographer's ~~trainee~~ assistant.

~~14~~31. "Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

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

~~15~~33. "Shielded position" means the location within the radiographic exposure device or ~~storage container which, by manufacturer's design, is the proper location for storage of the sealed source~~ source changer where the sealed source is secured and restricted from movement.

~~16~~34. "Shielded-room radiography" means industrial radiography conducted in a room so shielded that every location on the exterior meets the conditions specified in subsection 1 of section 33-10-04.1-07.

35. "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

~~17~~36. "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

~~18~~37. "Storage area" means any location, facility, or vehicle which is used to store, transport, or secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

~~19~~38. "Storage container" means a shielded device in which sealed sources are secured and stored.

~~20~~39. "Temporary jobsite" means ~~any location where industrial radiography is performed other than the locations listed in a specific license or certificate of registration~~ a

location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

~~21~~40. "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the United States department of transportation.

41. "Underwater radiography" means industrial radiography performed when the radiographic exposure device or related equipment are beneath the surface of the water.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-03.1. Exemptions.

1. Except for the requirements of subdivisions b and c of subsection 6 of section 33-10-05-06, certified cabinet X-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this chapter.

2. Industrial users of lixiscopes are exempt from the requirements of this chapter.

History: Effective March 1, 1994.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04

33-10-05-04. Equipment control.

1. Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

   a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American national standards institute (ANSI) N432-1980 "radiological safety for the design and construction of apparatus for gamma radiography", (published in NBS handbook 136, issued January 1981). Engineering analysis may be submitted by

an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the department may find this an acceptable alternative to actual testing of the component pursuant to the standard.

b. In addition to the requirements specified in subdivision a, the following requirements apply to radiographic exposure devices ~~and associated equipment~~, source changers, source assemblies and sealed sources.

(1) The licensee shall ensure that ~~E~~each radiographic exposure device ~~must have~~ has attached to it ~~by the user,~~ a durable, legible, clearly visible label bearing the:

(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 number (or product code) and serial number of the sealed source;

(d) Manufacturer of the sealed source; and

(e) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as type B transport containers must meet the applicable requirements of 10 CFR part 71.

(3) Modification of ~~any exposure devices~~ radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in subdivisions a and b, 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 ~~routine operation~~ 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, lockbox, 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 in it, a durable, legible, visible label with the words: "DANGER RADIOACTIVE". The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must ~~have passed the~~ be able to withstand a crushing test~~s for the control tube as specified in American national standards institute N432-1980~~ and a kinking resistance test that closely approximates the crushing and kinking forces 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 assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in American national standards institute N432-1980.

(9) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

d. Notwithstanding subdivision a, 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 realistically exert on the lever or crankshaft of the drive mechanism.

2. **Limits on ~~levels of radiation for radiographic exposure devices and storage containers~~ <u>external radiation levels from storage containers and source changers</u>.** <u>The maximum exposure rate limits for storage containers and source changers are two millisieverts (200 millirem) per hour at any exterior surface, and one tenth millisievert (10 millirem) per hour at one meter from any exterior surface with the sealed source in the shielded position.</u>

~~a. Radiographic exposure devices measuring less than ten centimeters [4 inches] from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of one hundred twenty-nine ten millionths coulombs per kilogram [50 milliroentgens] per hour at fifteen centimeters [6 inches] from any exterior surface of the device. Radiographic exposure devices measuring a minimum of ten centimeters [4 inches] from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of five hundred sixteen ten millionths coulombs per kilogram [200 milliroentgens] per hour at any exterior surface, and two hundred fifty hundred millionths coulombs per kilogram [10 milliroentgens] per hour at one meter [39.4 inches] from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.~~

~~b. Subdivision a of this subsection applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers must meet the requirements of subsection 1, and subsection 2 applies only to storage containers and source changers.~~

3. **Locking of ~~sources of radiation~~ <u>radiographic exposure devices, storage containers and source changers</u>.**

a. Each ~~source of radiation~~ <u>radiographic exposure device</u> shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production

of radiation or removal or exposure of a sealed source and shall be kept locked (and if a keyed-lock, with the key removed at all times) at all times except when under the direct surveillance of a radiographer or radiographer's ~~trainee~~ assistant, or as may be otherwise authorized pursuant to subsection 1 of section 33-10-05-06. Each storage container and source changer likewise shall be provided with a lock and must be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or ~~radiographer trainee~~ radiographer's assistant.

b. Radiographic exposure devices, source changers and storage containers, prior to being moved from one location to another and also prior to being secured to a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

c. The sealed source must be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey must be performed to determine that the sealed source is in the shielded position pursuant to subdivision b of subsection 3 of section 33-10-05-06.

4. **Storage precautions.**

a. Locked radiographic exposure devices, source changers, storage containers, and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.

b. Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary jobsites, if the licensee complies with subdivision c, and if the vehicle does not constitute a permanent storage location as described in subdivision d.

c. If a vehicle is to be used for storage of radioactive material, a vehicle survey must be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in subsection 3 of section 33-10-04.1-16 at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than ninety

days and any one or more of the following applies to the location:

(1) Telephone service is established by the licensee.

(2) Industrial radiographic services are advertised for or from the location.

(3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

5. **Radiation survey instruments.**

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and chapter 33-10-04.1. Instrumentation required by this subsection must ~~have a range such that five hundred sixteen billionths coulombs per kilogram [2 milliroentgens] per hour through two hundred fifty millionths coulombs per kilogram [1 roentgen] per hour can be measured~~ be capable of measuring a range from two hundredths millisievert (2 millirem) per hour through one hundredth sievert (1 rem) per hour.

b. Each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed ~~three months and after each instrument servicing~~ six months and after instrument servicing, except for battery changes.

(2) Such that accuracy within plus or minus twenty percent can be demonstrated.

(3) At two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logithmic scale instruments; and ~~at appropriate points for digital instruments~~ for digital instruments, at three points between two hundredths and ten millisieverts (2 and 1000 millirem) per hour.

c. Records of these calibrations must be maintained for ~~two~~ three years after the calibration date for inspection by the department.

d. Each radiation survey instrument must be checked with a radiation source at the beginning of each day of use and

at the beginning of each workshift to ensure it is operating properly.

6. **Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.**

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the department, the United States nuclear regulatory commission, or any agreement state.

b. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six-month period prior to the transfer, the sealed source shall not be put into use until tested.

c. The leak test shall be capable of detecting the presence of one hundred eighty-five becquerels [0.005 microcurie] of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to paragraph 5 of subdivision a of subsection 3 of section 33-10-03-05. Records of leak test results shall be kept in units of becquerels [microcuries] and maintained for inspection by the department for ~~two~~ three years after the required leak test is performed.

d. Any test conducted pursuant to subdivisions b and c which reveals the presence of one hundred eighty-five becquerels [0.005 microcurie] or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with rules of the department. Within five days after obtaining results of the test, the licensee shall file a report with the department describing the equipment involved, the test results, and the corrective action taken.

e. ~~Each radiographic exposure device must have permanently attached to it a durable tag which has, as a minimum, the instruction: "Danger-Radioactive Material - Do Not Handle - Notify Civil Authorities if Found".~~

Each exposure device using depleted uranium shielding and an "S" tube configuration must be tested for depleted uranium contamination at intervals not to exceed twelve months. The analysis must be capable of detecting the presence of one hundred eighty-five becquerels (0.005 microcurie) of radioactive material on the test sample and must be analyzed by a person specifically authorized by the United States nuclear regulatory commission or another agreement state. Should this testing reveal the presence of one hundred eighty-five becquerels (0.005 microcurie) or more of removable depleted uranium contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. Depleted uranium shielded devices do not have to be tested for depleted uranium contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for depleted uranium contamination if the interval of storage exceeded twelve months. Records of depleted uranium leak tests must be kept in units of bequerels (microcuries) and maintained for inspection by the department for three years after the required test is performed.

7. **Quarterly inventory.** Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and radiography exposure devices containing depleted uranium received ~~or~~ and possessed by the licensee. The records of the inventories shall be maintained for ~~two~~ three years from the date of the inventory for inspection by the department and shall include the quantities and kinds of radioactive material, the location of sealed sources, the date of the inventory, the name of the individual conducting the inventory, the manufacturer, the model number, and the serial number.

8. **Utilization logs.** Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the department for ~~two~~ three years from the date of the recorded event, showing for each source of radiation the following information:

   a. A ~~unique identification, such as~~ description, including make, model and serial number, of each radiation machine, each radiographic exposure device, or transport or storage container in which a sealed source is located, and each sealed source.

   b. The identity and signature of the radiographer to whom assigned.

c. Locations where used and dates of use.

d. The dates each source of radiation is removed from storage and returned to storage.

9. **Inspection and maintenance.**

~~a. Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day or shift the equipment is used.~~

~~b. Each licensee or registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with the manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the department for two years from the date the inspection and maintenance is performed.~~

a. The licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means.

b. Each licensee shall have written procedures for:

(1) Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

(2) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The 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.

c. If any inspection conducted pursuant to subdivision a or b reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until replaced or repairs have been made.

d. Records of inspection and maintenance shall be maintained for inspection by the department for three years from the date the inspection and maintenance is performed.

10. **Permanent radiographic installations.** Permanent radiographic installations having high radiation area entrance controls of the type described in subsection 1 of section 33-10-04.1-10 shall also meet the following requirements:

a. Each entrance that is used for personnel access to the high radiation area shall have either:

(1) An entrance control of the type described in section 33-10-04.1-10 that reduces the radiation level upon entry into the area, or

(2) ~~b~~Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

b. ~~The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it must be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the department for two years from the date the tests were conducted.~~ The control device or 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 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 seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements

continuous surveillance and uses an alarming ratemeter. Records of these tests shall be maintained for inspection by the department for three years from the date the tests were conducted.

11. **Reporting requirements.**

a. In addition to the reporting requirements specified in subsection 5 of section 33-10-04.1-16 and under other sections of this chapter, each licensee shall provide a written report to the department, within thirty days of the occurrence of any of the following incidents involving radiographic equipment:

(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 (critical to safe operation of the device) to properly perform its intended function.

b. The licensee shall include the following information in each report submitted under subdivision a:

(1) A description of the equipment problem.

(2) Cause of each incident, if known.

(3) Manufacturer and model number of equipment involved in the incident.

(4) Place, time, and date of the incident.

(5) Actions taken to establish normal operations.

(6) Corrective actions taken or planned to prevent recurrence.

(7) Qualifications of personnel involved in the incident.

c. Reports of overexposure submitted under subsection 3 of section 33-10-04.1-16 which involve failure of safety components of radiography equipment must also include the information specified in subdivision b.

d. Any licensee conducting radioagraphic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the department prior to exceeding the 180 days.

12. **Labeling, storage, and transportation.**

a. The licensee may not use a radiographic exposure device, source changer or a container to store licensed material unless the radiographic exposure device, 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 millimeter, and the wording:

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

b. The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Chapter 33-10-13.

c. Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

d. The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-05. Personal radiation safety requirements for radiographic personnel.

1. **Conducting industrial radiographic operations.**

a. 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 for and is designated as a radiographer's assistant. The additional qualified individual shall 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.

b. All radiographic operations conducted at locations of use authorized in the license must be conducted within a permanent radiographic installation, unless specifically authorized by the department.

c. A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the department, the United States nuclear regulatory commission or by another agreement state.

2. **Radiation safety officer for industrial radiography.** The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

a. 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 33-10-05-05.3;

(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 protection program.

b. The department will consider alternatives when the radiation safety officer has appropriate training and/or 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.

c. The specific duties and authorities of the radiation safety officer include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by this article, and reviewing them regularly to ensure that the procedures in use conform to department regulations and to the license conditions.

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring 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 and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 33-10-05-05.5; and

(5) Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

~~1~~3. **Training and testing.**

a. The licensee or registrant shall not permit any individual to act as a ~~radiographer trainee until such individual has received copies of, instructions in, and has demonstrated an understanding of~~ radiographer's assistant until the individual:

(1) ~~The subjects outlined in appendix A of this chapter;~~ Has received copies of and instructions in the subjects outlined in appendix A of this chapter, the rules contained in this chapter and in the applicable sections of chapters 33-10-04.1, 33-10-10 and 33-10-13, the appropriate department license or certificate of registration; and the licensee's or registrant's operating and emergency procedures.

(2) ~~The rules contained in this chapter and in the applicable sections of chapters 33-10-04.1, 33-10-10 and 33-10-13;~~ Has developed competence to use,

under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

(3) ~~The appropriate department license or certificate of registration, and~~ Has demonstrated understanding of the instructions provided under paragraph (1) of this subdivision by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in paragraph (2) of this subdivision by successful completion of a practical examination on the use of such hardware.

(4) Has demonstrated an understanding of ~~The~~ the licensee's or registrant's operating and emergency procedures.

b. The licensee or registrant shall not permit any individual to act as a radiographer, as defined in this chapter, unless such individual:

(1) Has met the requirements of subdivision a of subsection ~~1~~ 3;

(2) Has completed at least ~~thirty days of on-the-job training by a radiographer instructor as a radiographer trainee~~ two months of on-the-job training as a radiographer's assistant following completion of the requirements of subdivision a of subsection ~~1~~ 3;

Note: This requirement does not apply to individuals designated as radiographers prior to March 1, 1992.

(3) Has received, training in the use of 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.

(~~3~~4) Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments by successful completion of a practical examination covering this material;

~~(4) Has demonstrated an understanding of the instructions in subdivision a of subsection 1 3 by~~

~~successful completion of a written test and a field examination on the subjects covered; and~~

(5) Has successfully completed, within the last five years, a radiographer certification examination ~~an examination~~ administered by the department or ~~a third party designated by the department~~ another certifying entity.

(6) Possesses a current ~~identification card issued pursuant to subsection 5 issued by the department or other certifying entity recognized~~ industrial radiographer identification card issued pursuant to subsection 7 by the department or other certifying entity.

c. ~~Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained by the licensee or registrant for inspection by the department for three years following termination of employment.~~ The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

d. ~~Each licensee or registrant shall conduct an internal audit program to ensure that the department's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the department for two years from the date of the audit.~~ Except as provided in paragraph(4), the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer assistant to ensure that regulations, the license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(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 paragraph (3) of subdivision b and the radiographer's assistant must re-demonstrate knowledge of the training requirements of paragraph (2) of subdivision a by a practical examination before these individuals can next participate in a radiographic operation.

(3) The department 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.

e. The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance indefinitely, or at least three years from the individual's termination of employment. Records of internal audits of radiographers and radiographer assistants shall be maintained for inspection by the department for three years from the date of the audit.

~~2~~4. **Operating and emergency procedures.**

a. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

~~a.~~ (1) The handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in chapter 33-10-04.1.

~~b.~~ (2) Methods and occasions for conducting radiation surveys.

~~c.~~ (3) Methods for controlling access to radiographic areas.

~~d.~~ (4) Methods and occasions for locking and securing sources of radiation.

~~e.~~ (5) Personnel monitoring and the use of personnel monitoring equipment~~, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale~~.

~~f.~~ (6) ~~Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation.~~ Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed and control of the sealed sources during transportation.

~~g.~~ (7) Minimizing exposure of individuals in the event of an accident.

~~h.~~ (8) The procedure for notifying proper personnel in the event of an accident.

~~i.~~ (9) Maintenance of records.

~~j.~~ (10) The inspection, ~~and~~ maintenance and operability checks of radiographic exposure devices, ~~source changers, storage containers, and radiation machines~~ survey instruments, transport containers, storage containers and radiation machines.

(11) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

(12) The procedures for identifying and reporting equipment defects and noncompliant activities.

(13) Source recovery procedures, if the licensee will perform source recovery.

b. The licensee or registrant shall maintain copies of current operating and emergency procedures until license termination. Superceded material must be retained for three years after the change has been made.

~~3. **Personnel monitoring control.**~~

~~a. The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer trainee unless, at all times during radiographic operations, each such individual wears a direct-reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to at least fifty-six~~

~~millionths coulombs per kilogram [200 milliroentgens] and shall be recharged daily or at the start of each shift. Each badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.~~

~~b. Pocket dosimeters shall be read and exposures recorded at least once daily.~~

~~c. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus thirty percent of the true radiation exposure. Records of this check must be maintained for inspection by the department for two years from the date of the annual check for correct response.~~

~~d. If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or thermoluminescent dosimeter must be processed immediately. The individual must not return to work with sources of radiation until a determination of the radiation exposure has been made.~~

~~e. Reports received from the film badge or thermoluminescent dosimeter processor and records of daily pocket dosimeter readings shall be kept for inspection by the department until the department authorizes disposition.~~

~~f. If a film badge or thermoluminescent dosimeter is lost or damaged, the worker shall cease work immediately until a replacement film badge or thermoluminescent dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or thermoluminescent dosimeter.~~

~~g. Each alarm ratemeter must:~~

~~(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;~~

~~(2) Be set to give an alarm signal at a preset dose rate of one hundred twenty-nine millionths coulombs per kilogram [500 milliroentgens] per hour;~~

~~(3) Require special means to change the preset alarm function; and~~

~~(4) Be calibrated at periods not to exceed one year for correct response to radiation. Acceptable ratemeters~~

~~must alarm within plus or minus twenty percent of the true radiation dose rate.~~

5. **Personnel Monitoring.**

(a) 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 combination of direct reading dosimeter, an operating alarm 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 wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to two millisieverts (200 millirem) 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 approved personnel dosimeters must be replaced at intervals not to exceed three months.

(4) After replacement, each personnel dosimeter must be processed as soon as possible.

(b) 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 for inspection by the department for three years from the date of the reading.

(c) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed twelve months for correct response to radiation, and records must be maintained for inspection by the department for three years from the date of the annual response check. Acceptable dosimeters must read within plus or minus twenty percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than two millisieverts (two hundred

millirem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within twenty-four 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 for inspection by the department until license termination.

(e) If the personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement film badge, TLD or other department approved monitoring badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge, TLD or other department approved monitoring badge. The results of the calculated exposure and the time period for which the film badge, TLD or other department approved monitoring badge was lost or damaged must be included in the records maintained for inspection by the department until license termination.

(f) Reports received from the accredited NVLAP personnel dosimeter processor must be retained for inspection by the department until license termination.

(g) Each alarm ratemeter must-

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of five mSv/hr (five hundred mrem/hr); with an accuracy of plus or minus twenty percent 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 twelve months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations for three years from the date of calibration.

~~4~~6. **Supervision of radiographer's ~~trainee~~ assistants.** Whenever a radiographer's ~~trainee~~ assistant uses radiographic exposure devices, sealed sources or related ~~source handling tools~~

equipment, or conducts radiation surveys required by subdivisions b and c of subsection 3 of section 33-10-05-06 to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's ~~trainee~~ assistant shall be under the personal supervision of a radiographer ~~instructor~~. The personal supervision must include:

(a) The radiographer's physical presence at the site where the sealed sources are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer's direct observation of the assistant's performance of the operations referred to in this subsection.

~~5~~7. **Identification card.**

a. An identification card will be issued to each individual who:

(1) Provides the department with documentation showing completion of;

(a) The radiographer's ~~trainee~~ assistant training requirements in subdivision a of subsection ~~1~~ 3.

(b) The radiographer on-the-job training and the demonstration of competence requirements in paragraphs 2, 3, and 4 of subdivision b of subsection ~~1~~ 3.

(2) The requirements in paragraph 1 do not apply to individuals designated as radiographers prior to March 1, 1992.

(3) Has successfully completed, within the last five years, the examination required in paragraph 5 of subdivision b of subsection ~~1~~ 3.

b. Suspension, revocation, or denial. An identification card may be suspended, revoked, or denied if:

(1) Violations of the requirements of this article are noted;

(2) Another certifying entity has revoked, suspended or denied an identification card for violations of applicable standards.

c. Expiration of the identification card. The identification card will expire five years from the date that the individual successfully completed the examination required in paragraph 5 of subdivision b of subsection ~~1~~ 3.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-06. Precautionary procedures in radiographic operations.

1. **Security.** During each radiographic operation, the radiographer or ~~radiographer trainee shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in chapter 33-10-01, except:~~ other individual present, as required by subsection 33-10-05-05.1, shall maintain continuous direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in chapter 33-10-01, except at permanent radiographic installations where all entryways are locked and the requirements of 33-10-05-04.10 are met.

   ~~a. Where the high radiation area is equipped with a control device or alarm system as described in subsection 1 of section 33-10-04.1-10.~~

   ~~b. Where the high radiation area is locked to protect against unauthorized or accidental entry.~~

2. **Posting.** ~~Notwithstanding any provisions in subdivision c of subsection 3 of section 33-10-04.1-13, areas in which radiography is being performed shall be conspicuously posted as required by subsection 2 of section 33-10-04.1-13.~~ All areas in which industrial radiography is being performed must be conspicuously posted as required by subsection 2 of section 33-10-04.1-13. Exceptions listed in subsection 3 of section 33-10-04.1-13 do not apply to industrial radiographic operations.

3. **Radiation surveys and survey records.**

   a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in subsection 5 of section 33-10-05-04 is

available and used at each site where radiographic exposures are made.

b. A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the entire length of the guide tube.

c. A survey must be made of the storage area as defined in section 33-10-05-03 whenever a radiographic exposure device is being placed in storage.

d. A physical radiation survey, as specified in subsection 3 of section 33-10-05-04, shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container, or source changer in a storage area as defined in section 33-10-05-03.

e. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off".

f. Records shall be kept of the surveys required by subdivisions c and d of subsection 3. Such records shall be maintained for inspection by the department for ~~two~~ three years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey must be maintained until the department authorizes their disposition.

4. **Documents and records required at temporary jobsites.** Each licensee or registrant conducting industrial radiography at a temporary jobsite or field station shall have the following records available at that site for inspection by the department:

a. Appropriate license or certificate of registration or equivalent document.

b. Operating and emergency procedures.

c. Applicable rules.

d. Survey records required pursuant to subsection 3 for the period of operation at the site.

e. Daily pocket dosimeter records for the period of operation at the site.

f. The latest instrument calibration and leak test record for specific devices in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter.

g. Utilization records for each radiographic exposure device dispatched from that location.

h. Records of equipment problems identified in daily checks of equipment.

i. Records of alarm system and entrance control checks if applicable.

j. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters.

k. The shipping papers for transportation of radioactive material.

l. When operating under reciprocity, a copy of the U.S. nuclear regulatory commission or agreement state license authorizing the use of radioactive material.

5. **Specific requirements for radiographic personnel performing industrial radiography.**

a. At a jobsite, the following must be supplied by the licensee or registrant:

(1) At least one operable, calibrated survey instrument;

(2) A current whole body personnel ~~monitor (thermoluminescent dosimeter or film badge)~~ dosimeter that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor for each individual;

(3) An operable, calibrated pocket dosimeter with a range of zero to ~~five hundred sixteen ten millionths coulombs per kilogram~~ two millisieverts [200 milliroentgens] for each worker;

(4) An alarm ratemeter set to give an alarm signal at a preset dose rate of ~~one hundred twenty-nine~~

~~millionths coulombs per kilogram~~ five millisieverts [500 milliroentgens] per hour; and

(5) The appropriate barrier ropes and signs.

b. Industrial radiographic operations must not be performed if any of the items specified in subdivision a of this subsection ~~5~~ are not available at the jobsite or are inoperable.

c. Each licensee or registrant shall provide as a minimum two radiographic personnel when sources of radiation are used at temporary jobsites as described in 33-10-05-05.1. ~~If one of the personnel is a radiographer trainee, the other must be a radiographer instructor.~~

d. No individual other than a radiographer or a radiographer's ~~trainee~~ assistant ~~who is~~ under the personal supervision of a radiographer ~~instructor must~~ may manipulate controls or operate equipment used in industrial radiographic operations.

~~e. No individual may act as a radiographer instructor unless such individual:~~

~~(1) Has met the requirements of subdivision b of subsection 1 of section 33-10-05-05;~~

~~(2) Has one year of documented experience as a radiographer; and~~

~~(3) Has been named as a radiographer instructor on the license or registration certificate issued by the department.~~

~~f~~e. During an inspection by the department, the department inspector may terminate an operation if any of the items required in subdivision a of this subsection ~~5~~ are not available ~~and~~ or operable, or if the required number of radiographic personnel are not present. Operations may not be resumed until such conditions are met.

6. **Special requirements and exemptions for cabinet radiography.**

a. Systems for cabinet radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this chapter and subsection 1 of section 33-10-04.1-07. If such a system is a certified cabinet X-ray

system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in paragraph 1. Records of these evaluations shall be maintained for inspection by the department for a period of ~~two~~ three years after the evaluation.

b. Certified cabinet X-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this chapter except that:

(1) Operating personnel must be provided with ~~either a film badge or a thermoluminescent dosimeter~~ a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor and reports of the results must be maintained for inspection by the department.

(2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the department until disposition is authorized by the department.

(3) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted and recorded in accordance with subsection 10 of section 33-10-05-04.

(4) The registrant shall perform an evaluation at intervals not to exceed one year, to determine conformance with subsection 1 of section 33-10-04.1-07. If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the department for a period of ~~two~~ three years after the evaluation.

c. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the department pursuant to subsection 1 of section 33-10-01-05.

7. **Prohibitions.** Industrial radiography performed with a sealed source which is not fastened to or contained in radiographic exposure devices, known as fishpole radiography, is prohibited unless specifically authorized by the department.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

APPENDIX A

SUBJECTS FOR INSTRUCTION OF RADIOGRAPHER'S ~~TRAINEES~~ ASSISTANTS

Training provided to qualify individuals as radiographer's ~~trainees~~ assistants in compliance with subdivision a of subsection ~~1~~ 3 of section 33-10-05-05 shall be presented on a formal basis. The training must include the following subjects:

1. Fundamentals of radiation safety

    a. Characteristics of radiation

    b. Units of radiation dose (mrem ~~or~~ and sievert) and quantity of radioactivity (curie ~~or~~ and becquerel)

    c. Significance of radiation dose

        (1) Radiation protection standards

        (2) Biological effects of radiation

        (3) Case histories of radiography accidents

    d. Levels of radiation from ~~sources of radiation~~ licensed material

    e. Methods of controlling radiation dose

        (1) Working time

        (2) Working distances

        (3) Shielding

2. Radiation detection instrumentation to be used

    a. Use of radiation survey instruments

        (1) Operation

        (2) Calibration

        (3) Limitations

b. Survey techniques

c. Use of personnel monitoring equipment

(1) ~~Film badges~~ Personnel dosimeters

(2) ~~Thermoluminescent dosimeters (TLD's)~~ Alarming rate meters

(3) Pocket dosimeters

(4) Other monitoring equipment

3. The requirements of pertinent federal and state rules and regulations

4. The licensee's or registrant's written operating and emergency procedures

5. Radiographic equipment to be used

a. Remote handling equipment

b. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails)

c. Storage and transport containers, source ~~chargers~~ changers

d. Operation and control of X-ray equipment

e. Collimators

f. Storage, control and disposal of licensed material

g. Inspection and maintenance of equipment

History: Amended effective October 1, 1982, June 1, 1986; June 1, 1992.

Appendix B
Radiographer Certification

I. Requirements for an Independent Certifying Organization

An independent certifying organization shall:

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

2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;

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 fields 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 department, 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 department 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 appendix A or equivalent U.S. nuclear regulatory commission or agreement state 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 appendix A or equivalent U.S. nuclear regulatory commission or agreement state regulations; (b) satisfactorily completed a minimum period of on-the-job training; and (c) has received verification by an agreement state or a U.S. nuclear regulatory commission 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, revoking, suspending, and reinstating a certificate;

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.

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 appendix A or equivalent Agreement State requirements;

2. Written in a multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in appendix A.

~~CHAPTER 33-10-07~~
~~USE OF RADIONUCLIDES~~
~~IN THE HEALING ARTS~~

~~Section~~
~~33-10-07-01 Purpose & Scope~~
~~33-10-07-01.1 Definitions~~
~~33-10-07-02 Interstitial, Intracavitary, and Superficial Applications [Repealed]~~
~~33-10-07-03 Teletherapy [Repealed]~~
~~33-10-07-03.1 General Regulatory Requirements~~
~~33-10-07-04 Additional Requirements~~
~~33-10-07-05 Specific Requirements~~
~~33-10-07-06 Specific Requirements for the Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies~~
~~33-10-07-07 Specific Requirements for the Use of Radiopharmaceuticals, Generators and Reagent Kits for Imaging and Localization Studies~~
~~33-10-07-08 Specific Requirements for the Use of Radiopharmaceuticals for Therapy~~
~~33-10-07-09 Specific Requirements for the Use of Sealed Sources for Diagnosis~~
~~33-10-07-10 Specific Requirements for the Use of Sources for Brachytherapy~~
~~33-10-07-11 Specific Requirements for the Use of a Sealed Source in Teletherapy~~
~~33-10-07-12 Specific Requirements for Training~~

~~**33-10-07-01. Purpose and scope.** This chapter 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 this chapter are in addition to, and not in substitution for, other requirements in this article. The requirements and provisions of this article apply to applicants and licensees subject to this chapter unless specifically exempted.~~

~~**History:** Amended effective June 1, 1986; June 1, 1992; March 1, 1994.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-01.1. Definitions.** As used in this chapter, the following definitions apply:~~

~~1. "Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.~~

~~2. "Authorized nuclear pharmacist" means a pharmacist who is:~~

~~a. Board certified as a nuclear pharmacist by the board of pharmaceutical specialties;~~

~~b. Identified as an authorized nuclear pharmacist on a United States nuclear regulatory commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or~~

~~c. Identified as an authorized nuclear pharmacist on a permit issued by a United States nuclear regulatory commission or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.~~

~~3. "Authorized user" means a physician, dentist, or podiatrist who is:~~

~~a. Board certified by at least one of the following boards:~~

~~(1) American board of nuclear medicine.~~

~~(2) American board of radiology.~~

~~(3) American osteopathic board of nuclear medicine.~~

~~(4) American osteopathic board of radiology.~~

~~(5) British facility of radiology or British royal college of radiology.~~

~~(6) Canadian royal college of physicians and surgeons;~~

~~b. Identified as an authorized user on a United States~~

~~nuclear regulatory commission or agreement state license that authorizes the medical use of radioactive material; or~~

~~c. Identified as an authorized user on a permit issued by a United States nuclear regulatory commission or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material.~~

~~4. "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.~~

~~5. "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.~~

~~6. "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.~~

~~7. "Management" means the chief executive officer or that individual's designee.~~

~~8. "Medical institution" means an organization in which several medical disciplines are practiced.~~

~~9. "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.~~

~~10. "Misadministration" means the administration of:~~

~~a. A radiopharmaceutical dosage greater than one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131:~~

~~(1) Involving the wrong individual or wrong radiopharmaceutical; or~~

~~(2) When both the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds one thousand one hundred ten kilobecquerels [30 microcuries].~~

~~b. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131.~~

~~(1) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or~~

~~(2) When the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage.~~

~~c. A gamma stereotactic radiosurgery radiation dose.~~

~~(1) Involving the wrong individual or wrong treatment site; or~~

~~(2) When the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.~~

~~d. A teletherapy radiation dose.~~

~~(1) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;~~

~~(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;~~

~~(3) When the calculated weekly administered dose exceeds the weekly prescribed dose by thirty percent or more of the weekly prescribed dose; or~~

~~(4) When the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose.~~

~~e. A brachytherapy radiation dose:~~

~~(1) 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);~~

~~(2) Involving a sealed source that is leaking;~~

~~(3) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or~~

~~(4) When the calculated administered dose differs from the prescribed dose by more than twenty percent of the prescribed dose.~~

~~f. A diagnostic radiopharmaceutical dosage, other than quantities greater than one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131, both:~~

~~(1) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and~~

~~(2) When the dose to the individual exceeds fifty millisieverts [5 rems] effective dose equivalent or five hundred millisieverts [50 rems] dose equivalent to any individual organ.~~

~~11. "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.~~

~~12. "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.~~

~~13. "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.~~

~~14. "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented.~~

~~a. In a written directive; or~~

~~b. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.~~

~~15. "Prescribed dose" means:~~

~~a. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;~~

~~b. For teletherapy, the total dose and dose per fraction as documented in the written directive; or~~

~~c. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.~~

~~16. "Recordable event" means the administration of:~~

~~a. A radiopharmaceutical or radiation without a written directive where a written directive is required;~~

~~b. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;~~

~~c. A radiopharmaceutical dosage greater than one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131 when both:~~

~~(1) The administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage; and~~

~~(2) The difference between the administered dosage and prescribed dosage exceeds five hundred fifty-five kilobecquerels [15 microcuries];~~

~~d. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;~~

~~e. A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by fifteen percent or more of the weekly prescribed dose; or~~

~~f. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.~~

~~17. "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.~~

~~18. "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.~~

~~19. "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.~~

~~20. "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 subdivision f, containing the following information.~~

~~a. For any administration of quantities greater than one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131: the dosage;~~

~~b. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;~~

~~c. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;~~

~~d. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;~~

~~e. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or~~

~~f. For all other brachytherapy:~~

~~(1) Prior to implantation: the radioisotope, number of sources, and source strengths; and~~

~~(2) 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).~~

~~**History**: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; May 1, 1998.~~
~~**General Authority**: NDCC 23-20.1-04~~
~~**Law Implemented**: NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-02. Interstitial, intracavitary, and superficial applications**. Repealed effective June 1, 1992.~~

~~**33-10-07-03. Teletherapy**. Repealed effective June 1, 1992.~~

~~**33-10-07-03.1. General Regulatory Requirements.**~~

~~1. **License required.**~~

~~a. No person may manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to this article.~~

~~b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with this chapter under the supervision of an authorized user as provided in subsection 5 of section 33-10-07-04.~~

~~c. Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with this chapter under the supervision of an authorized nuclear pharmacist or authorized users as provided in subsection 5 of section 33-10-07-04.~~

2. **License amendments.** A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this chapter;

b. Before the licensee permits 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 one of the following organizations:

(a) American board of nuclear medicine.

(b) American board of radiology.

(c) American osteopathic board of nuclear medicine.

(d) American osteopathic board of radiology.

(e) British faculty of radiology or British royal college of radiology.

(f) Canadian royal college of physicians and surgeons;

(2) An authorized nuclear pharmacist certified by the board of pharmaceutical specialties;

(3) Identified as an authorized user or an authorized nuclear pharmacist on a United States nuclear regulatory commission or an 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 a United States nuclear regulatory commission or an 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.

c. Before changing a radiation safety officer or teletherapy physicist;

d. Before the licensee orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license;

e. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

3. **Notifications.**

a. A licensee shall provide to the department a copy of the board certification, the United States nuclear regulatory commission or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than thirty days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to subdivision b of subsection 2.

b. A licensee shall notify the department by letter no later than thirty days after:

(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.

4. **Exemptions regarding type A specific licenses of broad scope.** A licensee possessing a type A specific license of broad scope for medical use is exempt from the following:

a. The provisions of subdivision b of subsection 2;

b. The provisions of subdivision e of subsection 2 regarding additions to or changes in the areas of use only at the addresses specified in the license;

~~c. The provisions of subdivision a of subsection 3; and~~

~~d. The provisions of paragraph 1 of subdivision b of subsection 3 for an authorized user or an authorized nuclear pharmacist.~~

~~**History:** Effective June 1, 1992; amended effective May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-04. Additional Requirements.**~~

~~1. **As low as is reasonably achievable program.**~~

~~a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable in accordance with subsection 2 of section 33-10-04.1-05.~~

~~b. To satisfy the requirement of subdivision a:~~

~~(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this article or the radiation safety committee; or~~

~~(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.~~

~~c. The as low as is reasonably achievable program must include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, 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 individuals make every reasonable effort to maintain occupational doses, doses to the~~

~~general public, and releases of radioactive material as low as is reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.~~

~~d. The licensee shall retain a current written description of the as low as is reasonably achievable program for the duration of the license. The written description must include:~~

~~(1) A commitment by management to keep occupational doses as low as is 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 the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and~~

~~(4) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 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.~~

~~2. **Radiation safety officer.**~~

~~a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall 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.~~

~~b. The radiation safety officer 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) 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 this article, a copy of this article, a copy of each licensing request and license and amendments, and the written policy and procedures required by this article; and~~

~~(3) 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 department for licensing action; or~~

~~(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.~~

~~3. **Radiation safety committee.** Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.~~

~~a. The committee must meet the following administrative requirements.~~

~~(1) Membership must consist of at least three individuals and shall 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.~~

~~(2) The committee shall meet at least once each calendar quarter.~~

~~(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.~~

~~(4) The minutes of each radiation safety committee meeting must include:~~

~~(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) Document any reviews required in subdivision c of subsection 1 and subdivision b of this subsection.~~

~~(5) The committee shall provide each member with a copy of the meeting minutes, and retain one copy until the department authorizes its disposition.~~

~~b. To oversee the use of licensed material, the committee shall:~~

~~(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as is reasonably achievable;~~

~~(2) (a) Review, on the basis of safety and with regard to the training and experience standards of this chapter, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;~~

~~(b) Review, pursuant to subdivision b of subsection 2 of section 33-10-07-03.1, 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 department 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;~~

~~(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and~~

~~(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.~~

~~4. **Statement of authorities and responsibilities.**~~

~~a. A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:~~

~~(1) Identify radiation safety problems;~~

~~(2) Initiate, recommend, or provide solutions; and~~

~~(3) Verify implementation of corrective actions.~~

~~b. A licensee shall establish, in writing, the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.~~

~~5. **Supervision.**~~

~~a. 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 section 33-10-07-03.1 shall:~~

~~(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;~~

~~(2) Review the supervised individual's use of radioactive material, provide reinstruction 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;~~

~~(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and~~

~~(5) Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients or human research subjects.~~

~~b. A licensee shall require the supervised individual receiving, possessing, using or transferring radioactive material under section 33-10-07-03.1 to:~~

~~(1) Follow the instructions of the supervising authorized user;~~

~~(2) Follow the written radiation safety and quality management procedures established by the licensee; and~~

~~(3) Comply with this article and the license conditions with respect to the use of radioactive material.~~

~~c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by subdivision c of subsection 1 of section 33-10-07-03.1, shall:~~

~~(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of~~

~~radioactive material;~~

~~(2) Require the supervised individual to follow the instructions given pursuant to paragraph 1 and to comply with this chapter and license conditions; and~~

~~(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.~~

~~d. A licensee that permits supervision of an individual is responsible for the acts and omissions of the supervised individual.~~

~~6. **Mobile nuclear medicine service administrative requirements.**~~

~~a. The department will only license mobile nuclear medicine services in accordance with this chapter and other applicable requirements of this article to serve clients who do not have a department license.~~

~~b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.~~

~~c. A mobile nuclear medicine service may not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.~~

~~7. **Quality management program.**~~

~~a. Each applicant or licensee under this chapter, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific~~

~~objectives.~~

~~(1) That, prior to administration, a written directive is prepared for:~~

~~(a) Any teletherapy radiation dose;~~

~~(b) Any gamma stereotactic radiosurgery radiation dose;~~

~~(c) Any brachytherapy radiation dose;~~

~~(d) Any administration of quantities greater than one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131; or~~

~~(e) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.~~

~~(If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within forty-eight hours of the oral revision.~~

~~Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.~~

~~If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented~~

~~immediately in the patient's record and a written directive is prepared within twenty-four hours of the oral directive.)~~

~~(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;~~

~~(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;~~

~~(4) That each administration is in accordance with the written directive; and~~

~~(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.~~

~~b. The licensee shall:~~

~~(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:~~

~~(a) A representative sample of patient and human research subject administrations;~~

~~(b) All recordable events; and~~

~~(c) All misadministrations;~~

~~to verify compliance with all aspects of the quality management program (these reviews must be conducted at intervals no greater than twelve months);~~

~~(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subdivision a of this section; and~~

~~(3) Retain records of each review, including the evaluations and findings of the review, in an~~

~~auditable form for three years.~~

~~c. The licensee shall evaluate and respond, within thirty days after discovery of the recordable event, to each recordable event by:~~

~~(1) Assembling the relevant facts including the cause;~~

~~(2) Identifying what, if any, corrective action is required to prevent recurrence; and~~

~~(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.~~

~~d. The licensee shall retain:~~

~~(1) Each written directive; and~~

~~(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph 1 of subdivision a, in an auditable form, for three years after the date of administration.~~

~~e. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the department within thirty days after the modification has been made.~~

~~f. (1) Each applicant for a new license, as applicable, shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.~~

~~(2) Each existing licensee, as applicable, shall submit to the department by January 1, 1995, a written certification that the quality management program has been implemented along with a copy of the program.~~

~~8. **Notifications, reports, and records of misadministrations.**~~

~~a. For a misadministration:~~

~~(1) The licensee shall notify the department by telephone no later than the next working day after discovery of the misadministration.~~

~~(2) The licensee shall submit a written report to the department within fifteen 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 include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this subsection, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.~~

~~(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that the referring physician 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 individual receiving the misadministration cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the~~

~~misadministration, because of any delay in notification.~~

~~(4) If the individual who received the misadministration was notified, the licensee shall also furnish, within fifteen days after discovery of the misadministration, a written report to the individual by sending either:~~

~~(a) A copy of the report that was submitted to the department; or~~

~~(b) 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 department can be obtained from the licensee.~~

~~b. Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that 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, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.~~

~~c. Aside from the notification requirement, nothing in this subsection affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.~~

~~9. **Suppliers for sealed sources or devices for medical use.** A licensee shall use for medical use only:~~

~~a. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to chapter 33-10-03 and subdivision j of subsection 5 of section 33-10-03-05, 10 CFR part 30 and 10 CFR 32.74, or the~~

~~equivalent requirements of another agreement state or a licensing state; or~~

~~b. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to this article, or the equivalent rules of another agreement state, a licensing state, or the United States nuclear regulatory commission.~~

~~10. **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 shall apply for and receive approval of a specific amendment to its department license before conducting such research. Both types of licensees shall, 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.~~

~~11. **Food and drug administration and other federal and state requirements.** Nothing in this chapter relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs or devices.~~

~~**History**: Effective June 1, 1992; amended effective March 1, 1994, July 1, 1995, May 1, 1998.~~
~~**General Authority**: NDCC 23-20.1-04~~
~~**Law Implemented**: NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-05. Specific requirements.**~~

~~1. **Quality control of imaging equipment.** Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures must include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the department. The licensee shall conduct quality control procedures in accordance with written procedures.~~

2. **Possession, use, calibration, and check of dose calibrators.**

a. A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.

b. A licensee shall:

(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 this section, the check shall be done on a frequently used setting with a sealed source of not less than three hundred seventy kilobecquerels [10 microcuries] of radium-226 or one thousand eight hundred fifty kilobecquerels [50 microcuries] of any other photon-emitting radionuclide with a half-life greater than ninety days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed twelve months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within five percent of the stated activity, with minimum activity of three hundred seventy kilobecquerels [10 microcuries] for radium-226 and one thousand eight hundred fifty kilobecquerels [50 microcuries] for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between one hundred thousand electron volts and five hundred thousand electron volts;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between one thousand one hundred ten kilobecquerels [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 shall keep a record of this test for the duration of the use of the dose calibrator.~~

c. ~~A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ten percent if the dosage is greater than one thousand one hundred ten kilobecquerels [30 microcuries] and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent.~~

d. ~~A licensee shall also perform checks and tests required by subdivision b following adjustment or repair of the dose calibrator.~~

e. ~~A licensee shall retain a record of each check and test required by this section for three years. The records required by subdivision b must include:~~

(1) ~~For paragraph 1 of subdivision b, 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 paragraph 2 of subdivision b, 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, and the identity of the individual performing the test;~~

(3) ~~For paragraph 3 of subdivision b, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test, and~~

(4) ~~For paragraph 4 of subdivision b, the model and serial number of the dose calibrator, the configuration of the source measured, the~~

~~activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.~~

~~3. **Possession, use, calibration and check of instruments to measure dosages of alpha-emitting or beta-emitting radionuclides.**~~

~~a. This subsection does not apply to unit dosages of alpha-emitting or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent regulations of an agreement state or a licensing state.~~

~~b. For other than unit dosages obtained pursuant to subdivision a, a licensee shall possess and use instrumentation to measure the radioactivity of alpha-emitting or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations the amount of radioactivity in dosages of alpha-emitting or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:~~

~~(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 consistency and proper operation at the beginning of each day of use.~~

~~4. **Calibration and check of survey instruments.**~~

~~a. A licensee shall ensure that the survey instruments used to show compliance with this section have been calibrated before first use, annually, and following repair.~~

~~b. To satisfy the requirements of subdivision a, the~~

~~licensee shall:~~

~~(1) Calibrate all required scale readings up to ten millisieverts [1000 millirems] per hour with a radiation source;~~

~~(2) For each scale that must be calibrated, calibrate two readings separated by at least fifty percent of scale rating; 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.~~

~~c. To satisfy the requirements of subdivision b, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than twenty percent, and shall conspicuously attach a correction chart or graph to the instrument.~~

~~d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.~~

~~e. The licensee shall retain a record of each calibration required in subdivision a 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.~~

~~f. To meet the requirements of subdivisions a, b, and c the licensee may obtain the services of individuals licensed by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations~~

~~which contain information required by subdivision e must be maintained by the licensee.~~

~~5. **Assay of radiopharmaceutical dosages**. A licensee shall:~~

~~a. Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use.~~

~~b. Measure by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha-emitting or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 37.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements;~~

~~c. Retain a record of the measurements required by subdivision a and b for three years. To satisfy this requirement, the record must contain the:~~

~~(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 a notation that the total activity is less than one thousand one hundred ten kilobecquerels [30 microcuries];~~

~~(4) Date and time of the measurement; and~~

~~(5) Initials of the individual who made the record.~~

~~6. **Authorization for calibration and reference sources**. Any person authorized by subsection 1 of section 33-10-07-03 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:~~

~~a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to chapter~~

~~33-10-03 or equivalent provisions of the United States nuclear regulatory commission, agreement state, or licensing state and that do not exceed five hundred fifty-five megabecquerels [15 millicuries] each;~~

~~b. Any radioactive material listed in sections 33-10-07-06 and 33-10-07-07 with a half-life of one hundred days or less in individual amounts not to exceed five hundred fifty-five megabecquerels [15 millicuries];~~

~~c. Any radioactive material listed in sections 33-10-07-06 and 33-10-07-07 with a half-life greater than one hundred days in individual amounts not to exceed seven thousand four hundred kilobecquerels [200 microcuries] each; and~~

~~d. Technetium-99m in individual amounts not to exceed one thousand eight hundred fifty megabecquerels [50 millicuries].~~

~~7. **Requirements for possession of sealed sources and brachytherapy sources.**~~

~~a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the department and shall maintain the instructions for the duration of source use in a legible form convenient to users.~~

~~b. A licensee in possession of a sealed source shall assure that:~~

~~(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 department, another agreement state, a licensing state, or the United States nuclear regulatory commission.~~

c. To satisfy the leak test requirements of subdivision b, the licensee shall assure that:

(1) Leak tests are capable of detecting the presence of one hundred eighty-five becquerels [0.005 microcuries] of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of thirty-seven becquerels [0.001 microcurie] per twenty-four 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.

d. A licensee shall 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.

e. If the leak test reveals the presence of one hundred eighty-five becquerels [0.005 microcurie] or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these regulations; and

(2) File a report with the department within five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

f. 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 thirty days;~~

~~(2) Sources containing only radioactive material as a gas;~~

~~(3) Sources containing three thousand seven hundred kilobecquerels [100 microcuries] or less of beta or photon-emitting material or three hundred seventy kilobecquerels [10 microcuries] or less of alpha-emitting material;~~

~~(4) Seeds of iridium-192 encased in nylon ribbon, and~~

~~(5) Sources stored and not being used. The licensee shall, 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.~~

~~g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall 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.~~

~~h. A licensee in possession of a sealed source or brachytherapy source shall 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.~~

~~i. A licensee shall retain a record of each survey required in subdivision h 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.~~

~~8. **Syringe shields.**~~

~~a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.~~

~~b. A licensee shall 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.~~

~~9. **Syringe labels.** Unless utilized immediately, a licensee shall 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, or the patient's or human research subject's name.~~

~~10. **Vial shields.** A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.~~

~~11. **Vial shield labels.** A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.~~

~~12. **Surveys for contamination and ambient radiation dose rate.**~~

~~a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.~~

~~b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.~~

~~c. A licensee shall conduct the surveys required by subdivisions a and b so as to be able to measure~~

~~dose rates as low as one microsievert [0.1 millirem] per hour.~~

~~d. A licensee shall establish dose rate action levels for the surveys required by subdivisions a and b and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.~~

~~e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.~~

~~f. A licensee shall conduct the surveys required by subdivision e so as to be able to detect contamination on each wipe sample of two thousand disintegrations per minute [33.3 becquerels].~~

~~g. A licensee shall establish removable contamination action levels for the surveys required by subdivision e and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.~~

~~h. A licensee shall retain a record of each survey required by subdivisions a, b and e 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 [disintegrations per minute] per one hundred 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.~~

~~13. **Release of individuals containing radiopharmaceuticals or permanent implants.**~~

~~a. 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 five millisieverts [0.5 rem].~~

~~b. The licensee shall 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 one millisievert [0.1 rem]. If the dose to a breast-feeding infant or child could exceed one millisievert [0.1 rem] assuming there were no interruption of breast-feeding, the instructions shall also include:~~

~~(1) Guidance on the interruption or discontinuation of breast-feeding; and~~

~~(2) Information on the consequences of failure to follow the guidance.~~

~~c. The licensee shall 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 twenty-five hundredths at one meter;~~

~~(3) Using the biological or effective half-life; or~~

~~(4) Considering the shielding by tissue.~~

~~d. The licensee shall 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 five millisieverts [0.5 rem].~~

~~14. **Mobile nuclear medicine service technical requirements.** A licensee providing mobile nuclear medicine service shall:~~

a. ~~Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;~~

b. ~~Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;~~

c. ~~Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;~~

d. ~~Check survey instruments and dose calibrators as required in paragraph 1 of subdivision b of subsection 2, subdivisions d and e of subsection 2, subdivision d of subsection 3, and check all other transported equipment for proper function before medical use at each location of use;~~

e. ~~Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client location 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~~

f. ~~Retain a record of each survey required by subdivision e 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.~~

15. ~~**Storage of volatiles and gases.**~~

a. ~~A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.~~

b. ~~A licensee shall store and use a multidose container in a properly functioning fume hood.~~

~~16. **Decay-in-storage.**~~

~~a. A licensee may hold radioactive material for decay-in-storage before disposal in ordinary trash if the licensee:~~

~~(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.~~

~~b. For radioactive material disposed in accordance with subdivision a, the licensee shall 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 dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.~~

~~**History:** Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-06. Specific requirements for the use of unsealed radioactive material for uptake, dilution, or excretion studies.**~~

~~1. **Use of unsealed radioactive material for uptake,**~~

~~**dilution, or excretion studies.**~~

~~a. A licensee may use for uptake, dilution or excretion studies any unsealed radioactive material prepared for medical use that is either:~~

~~(1) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements; or~~

~~(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection 4 of section 33-10-07-12, or an individual under the supervision of either as specified in subsection 5 of section 33-10-07-04.~~

~~b. A licensee using a radiopharmaceutical specified in this subsection 1 for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.~~

~~2. **Possession of survey instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert [0.1 millirem] per hour to five hundredmicrosieverts [50 millirems] per hour. The instrument shall be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.~~

~~**History:** Effective June 1, 1992; amended effective May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-07. Specific requirements for the use of unsealed radioactive material for imaging and localization studies.**~~

~~1. **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:~~

~~a. Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements; or~~

~~b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection 4 of section 33-10-07-12, or an individual under the supervision of either as specified in subsection 5 of section 33-10-07-04.~~

~~2. **Permissible molybdenum-99 concentration.**~~

~~a. A licensee may not administer a radiopharmaceutical containing more than fifteen hundredths kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m [0.15 microcurie of molybdenum-99 per millicurie of technetium-99m].~~

~~b. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.~~

~~c. A licensee who must measure molybdenum concentration shall 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 megabecquerels [millicuries], the measured activity of molybdenum expressed in kilobecquerels [microcuries], the ratio of the measures expressed as kilobecquerels of molybdenum per megabecquerel of technetium [microcuries of molybdenum per millicurie of technetium], the date of the test, and the initials of the individual who performed the test.~~

~~d. A licensee shall report immediately to the department each occurrence of molybdenum-99 concentration exceeding the limits specified in subdivision a.~~

~~3. **Control of aerosols and gases.**~~

~~a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by sections 33-10-04.1-06 and 33-10-04.1-07.~~

~~b. 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.~~

~~c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.~~

~~d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in appendix B of chapter 33-10-04.1. The calculation must be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.~~

~~e. A licensee shall post the time calculated in subdivision d at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.~~

~~f. A licensee shall 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.~~

~~g. A copy of the calculations required in subdivision d must be recorded and retained for the duration of the license.~~

~~4. **Possession of survey instruments**. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert [0.1 millirem] per hour to five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten~~

~~microsieverts [1 millirem] per hour to ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.~~

~~**History:** Effective June 1, 1992; amended effective March 1, 1994, May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-08. Specific requirements for the use of unsealed radioactive material for therapeutic administration.**~~

~~1. **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:~~

~~a. Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements; or~~

~~b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection 4 of section 33-10-07-12, or an individual under the supervision of either as specified in subsection 5 of section 33-10-07-04.~~

~~2. **Safety instruction.**~~

~~a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy. Refresher training must be provided at intervals not to exceed one year.~~

~~b. To satisfy subdivision a, the instruction must describe the licensee's procedures for:~~

~~(1) Patient or human research subject control;~~

~~(2) Visitor control;~~

~~(3) Contamination control;~~

~~(4) Waste control; and~~

~~(5) Notification of the radiation safety officer or authorized user in case of the patient's or the human research subject's death or medical emergency.~~

~~c. A licensee shall keep a record of individuals receiving instruction required by subdivision a, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record must be maintained for inspection by the department for three years.~~

~~3. **Safety precautions.**~~

~~a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with subsection 13 of section 33-10-07-05, a licensee shall:~~

~~(1) Provide a private room with a private sanitary facility;~~

~~(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" 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 human research subject's room;~~

~~(3) Authorize visits by individuals under eighteen 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 chapter 33-10-04.1 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 millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey;~~

~~(5) Either monitor material and items removed from the patient's or 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, or handle these materials and items as radioactive waste;~~

~~(6) Survey the patient's or 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 two hundred disintegrations per minute [3.33 becquerels] per one hundred square centimeters; and~~

~~(7) 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 subdivision a of subsection 7 of section 33-10-04.1-15 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.~~

~~b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or the human research subject dies or has a medical emergency.~~

~~4. **Possession of survey instruments.** A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert [0.1 millirem] per hour to~~

~~five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range en microsieverts [1 millirem] per hour to ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.~~

~~**History:** Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-09. Specific requirements for the use of sealed sources for diagnosis.**~~

~~1. **Use of sealed sources for diagnosis.** A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:~~

~~a. Iodine-125 as a sealed source in a device for bone mineral analysis;~~

~~b. Americium-241 as a sealed source in a device for bone mineral analysis;~~

~~c. Gadolinium-153 as a sealed source in a device for bone mineral analysis; and~~

~~d. Iodine-125 as a sealed source in a portable device for imaging.~~

~~2. **Availability of survey instrument.** A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert [0.1 millirem] per hour to five hundred millisieverts [50 millirems] per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts [1 millirem] per hour to ten millisieverts [1000 millirems] per hour. The instrument must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.~~

~~**History:** Effective June 1, 1992; amended effective May 1, 1998.~~

~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-10. Specific requirements for the use of sources for brachytherapy.**~~

1. ~~**Use of sources for brachytherapy.** A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:~~

   a. ~~Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

   b. ~~Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

   c. ~~Gold-198 as a sealed source in seeds for interstitial treatment of cancer;~~

   d. ~~Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;~~

   e. ~~Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;~~

   f. ~~Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

   g. ~~Radon-222 as seeds for interstitial treatment of cancer;~~

   h. ~~Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and~~

   i. ~~Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.~~

2. ~~**Safety instruction.**~~

   a. ~~The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training must~~

~~be provided at intervals not to exceed one year.~~

~~b. To satisfy subdivision a, the instruction must describe:~~

~~(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, and~~

~~(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.~~

~~c. A licensee shall maintain a record of individuals receiving instruction required by subdivision a, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.~~

~~3. **Safety precautions.**~~

~~a. For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to subsection 13 of section 33-10-07-05, a licensee shall:~~

~~(1) Not place the patient or the human research subject in the same room with a patient or human research subject 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;~~

~~(3) Authorize visits by individuals under eighteen 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 implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with chapter 33-10-04.1 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 microsieverts [millirems] per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and~~

~~b. A licensee shall notify the radiation safety officer or authorized user immediately if the patient or the human research subject dies or has a medical emergency.~~

~~4. **Brachytherapy sources inventory.**~~

~~a. Promptly after removing brachytherapy sources from a patient or human research subject, a licensee shall 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.~~

~~b. A licensee shall make a record of brachytherapy source utilization which includes:~~

~~(1) The names of the individuals permitted to handle the sources;~~

~~(2) The number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date the brachytherapy sources 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 patient's or the human research subject's name and room number, the time and date the brachytherapy sources 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.~~

~~c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.~~

~~d. A licensee shall maintain the records required in subdivisions b and c for three years.~~

~~5. **Release of patients or human research subjects treated with temporary implants.**~~

~~a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.~~

~~b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with subdivision a for three years. Each record must include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as microsieverts [millirems] per hour and measured within one meter from the patient or human research subject, and the initials of the individual who made the survey.~~

~~6. **Possession of survey instruments.** A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument~~

~~capable of detecting dose rates over the range one microsievert [0.1 millirem] per hour to five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts [1 millirem] per hour to ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.~~

~~**History:** Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-11. Specific requirements for the use of a sealed source in teletherapy.**~~

~~1. **Use of a sealed source in a teletherapy unit.** A licensee shall 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.~~

~~2. **Maintenance and repair restrictions.** Only a person specifically licensed by the department, the United States nuclear regulatory commission, or an agreement state to perform teletherapy unit maintenance and repair shall 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.~~

~~3. **Amendments.** In addition to the requirements specified in section 33-10-07-03.1, a licensee shall apply for and receive a license amendment before:~~

~~a. Making any change in the treatment room shielding;~~

~~b. Making any change in the location of the teletherapy unit within the treatment room;~~

~~c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas~~

~~outside the teletherapy treatment room;~~

~~d. Relocating the teletherapy unit; or~~

~~e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.~~

~~4. **Safety instruction.**~~

~~a. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions must inform the operator of:~~

~~(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.~~

~~b. A licensee shall provide instruction in the topics identified in subdivision a to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.~~

~~c. A licensee shall maintain a record of individuals receiving instruction required by subdivision b, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.~~

~~5. **Doors, interlocks, and warning systems.**~~

~~a. A licensee shall control access to the teletherapy room by a door at each entrance.~~

~~b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:~~

~~(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;~~

~~(2) Turn the 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.~~

~~c. A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.~~

~~6. **Possession of survey instrument.** A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert [0.1 millirem] per hour to five hundred microsieverts [50 millirems] per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts [1 millirem] per hour to ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.~~

~~7. **Radiation monitoring device.**~~

~~a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.~~

~~b. Each radiation monitor must be capable of providing 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.~~

~~c. 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.~~

~~d. 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.~~

~~e. A licensee shall maintain a record of the check required by subdivision d for three years. The record must include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.~~

~~f. If a radiation monitor is inoperable, the licensee shall 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. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subdivision e.~~

~~g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.~~

~~8. **Viewing system**. A licensee shall 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.~~

~~9. **Dosimetry equipment**.~~

~~a. A licensee shall 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. 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; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the national institute of standards and technology or by a calibration laboratory accredited by the American association of physicists in medicine. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the American association of physicists in medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than two percent. 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 shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.~~

~~b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision a. 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 subdivision a.~~

~~c. The licensee shall 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 subdivisions a and b 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 American association of physicists in medicine.~~

~~10. **Full calibration measurements.**~~

~~a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:~~

~~(1) Before the first medical use of the unit;~~

~~(2) Before medical use under the following conditions:~~

~~(a) Whenever spot-check measurements indicate that the output differs by more than five percent 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.~~

~~b. To satisfy the requirement of subdivision a, full calibration measurements must include determination of:~~

~~(1) The output within three percent 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;~~

~~(5) "On-off" error, and~~

~~(6) The accuracy of all distance measuring and localization devices in medical use.~~

~~c. A licensee shall use the dosimetry system described in subsection 9 to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 1 of subdivision b may then be made using a dosimetry system that indicates relative dose rates.~~

~~d. A licensee shall make full calibration measurements required by subsection 1 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.~~

~~e. A licensee shall correct mathematically the outputs determined in paragraph 1 of subdivision b for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.~~

~~f. Full calibration measurements required by subdivision a and physical decay corrections required by subdivision e must be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the United States nuclear regulatory commission or an agreement state to perform such services.~~

~~g. A licensee shall 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, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.~~

~~11. **Periodic spot checks.**~~

~~a. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.~~

~~b. To satisfy the requirement of subdivision a, spot checks must include determination of:~~

~~(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 paragraph 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).~~

~~c. A licensee shall use the dosimetry system described in subsection 9 to make the spot check required in paragraph 5 of subdivision b.~~

d. ~~A licensee shall perform spot checks required by subdivision a in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.~~

e. ~~A licensee shall have the teletherapy physicist review the results of each output spot check within fifteen days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for three years.~~

f. ~~A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.~~

g. ~~To satisfy the requirement of subdivision f, safety spot checks shall assure proper operation of:~~

(1) ~~Electrical interlocks at each teletherapy room entrance;~~

(2) ~~Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;~~

(3) ~~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".~~

h. ~~A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee must use the unit until the interlock~~

~~system is repaired unless specifically authorized by the department.~~

~~i. A licensee shall promptly repair any system identified in subdivision g that is not operating properly. The teletherapy unit may not be used until all repairs are completed.~~

~~j. A licensee shall maintain a record of each spot check required by subdivisions a and f 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, the timer constancy and linearity, 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 timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated 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.~~

~~12. **Radiation surveys for teletherapy facilities.**~~

~~a. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by subsection 3, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with subsection 3 of section 33-10-07-05 to verify that:~~

~~(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 one hundred microsieverts [10 millirems] per hour and twenty microsieverts [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 subsection 1 of section 33-10-04.1-06, and~~

~~(b) Radiation levels in unrestricted areas do not exceed the limits specified in subsection 1 of section 33-10-04.1-07.~~

~~b. If the results of the surveys required in subdivision a indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:~~

~~(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 from the department.~~

~~c. A licensee shall 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 microsieverts [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.~~

~~13. **Safety spot checks for teletherapy facilities.**~~

a. ~~A licensee shall promptly check all systems listed in subdivision g of subsection 11 for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by subsection 3.~~

b. ~~If the results of the safety spot checks required in subdivision a indicate the malfunction of any system specified in subsection 11, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.~~

c. ~~A licensee shall 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, doors, and the signature of the radiation safety officer.~~

14. ~~**Modification of teletherapy unit or room before beginning a treatment program.** If the survey required by subsection 12 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by subsection 1 of section 33-10-04.1-07, before beginning the treatment program the licensee shall:~~

a. ~~Either equip the unit with stops or add additional radiation shielding to ensure compliance with subsection 1 of section 33-10-04.1-07;~~

b. ~~Perform the survey required by subsection 12 again, and~~

c. ~~Include in the report required by subsection 15 the results of the initial survey, a description of the modification made to comply with subdivision a, and the results of the second survey; or~~

d. ~~Request and receive a license amendment under subdivision c of subsection 1 of section 33-10-04.1-07 that authorizes radiation levels in unrestricted areas greater than those permitted by subdivision a of subsection 1 of section 33-10-~~

~~04.1-07.~~

~~15. **Reports of teletherapy surveys, checks, tests, and measurements.** A licensee shall furnish a copy of the records required in subsections 12, 13, and 14 and the output from the teletherapy source expressed as sieverts [rems] per hour at one meter from the source as determined during the full calibration required in subsection 10 to the department within thirty days following completion of the action that initiated the record requirement.~~

~~16. **Five-year inspection.**~~

~~a. A licensee shall 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.~~

~~b. This inspection and servicing may only be performed by persons specifically licensed to do so by the department, an agreement state, or the United States nuclear regulatory commission.~~

~~c. A licensee shall 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.~~

~~**History:** Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

~~**33-10-07-12. Specific requirements for training.**~~

~~1. **Radiation safety officer.** Except as provided in subsection 2 an individual fulfilling the responsibilities of the radiation safety officer as~~

~~provided in subsection 2 of section 33-10-07-04 shall:~~

~~a. Be certified by the:~~

~~(1) American board of health physics in comprehensive health physics;~~

~~(2) American board of radiology;~~

~~(3) American board of nuclear medicine;~~

~~(4) American board of science in nuclear medicine;~~

~~(5) Board of pharmaceutical specialties in nuclear pharmacy;~~

~~(6) American board of medical physics in radiation oncology;~~

~~(7) Royal college of physicians and surgeons of Canada in nuclear medicine;~~

~~(8) American osteopathic board of radiology; or~~

~~(9) American osteopathic board of nuclear medicine; or~~

~~b. Have had two hundred hours of classroom and laboratory training as follows:~~

~~(1) Radiation physics and instrumentation;~~

~~(2) Radiation protection;~~

~~(3) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(4) Radiation biology;~~

~~(5) Radiopharmaceutical chemistry; and~~

~~(6) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer by the department, an agreement state, licensing state, or United States nuclear regulatory commission license that authorizes the medical~~

~~use of radioactive material; or~~

~~c. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.~~

~~2. **Training for experienced radiation safety officer.** An individual identified as a radiation safety officer by the department, agreement state, licensing state, or United States nuclear regulatory commission license on October 1, 1986, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of subsection 1.~~

~~3. **Training for uptake, dilution, or excretion studies.** Except as provided in subsections 11 and 12, the licensee shall require the authorized user of a radiopharmaceutical listed in section 33-10-07-06 to be a physician who:~~

~~a. Is certified in:~~

~~(1) Nuclear medicine by the American board of nuclear medicine;~~

~~(2) Diagnostic radiology by the American board of radiology;~~

~~(3) Diagnostic radiology or radiology by the American osteopathic board of radiology;~~

~~(4) Nuclear medicine by the American osteopathic board of nuclear medicine; or~~

~~(5) Nuclear medicine by the royal college of physicians and surgeons of Canada; or~~

~~b. Has completed forty hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and twenty hours of supervised clinical experience.~~

~~(1) To satisfy the basic instruction requirement, forty hours of classroom and laboratory instruction must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

~~(d) Radiation biology; and~~

~~(e) Radiopharmaceutical chemistry.~~

~~(2) To satisfy the requirement for twenty hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:~~

~~(a) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~(c) Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~(e) 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 the topics identified in subdivision b.~~

~~4. **Training for imaging and localization studies.** Except as provided in subsections 11 and 12, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in section 33-10-07-07 to be a physician who:~~

~~a. Is certified in:~~

~~(1) Nuclear medicine by the American board of nuclear medicine;~~

~~(2) Diagnostic radiology by the American board of radiology;~~

~~(3) Diagnostic radiology or radiology by the American osteopathic board of radiology;~~

~~(4) Nuclear medicine by the American osteopathic board of nuclear medicine; or~~

~~(5) Nuclear medicine by the royal college of physicians and surgeons of Canada; or~~

~~b. Has completed two hundred hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, five hundred hours of supervised work experience, and five hundred hours of supervised clinical experience:~~

~~(1) To satisfy the basic instruction requirement, two hundred hours of classroom and laboratory training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

~~(d) Radiopharmaceutical chemistry; and~~

~~(e) Radiation biology.~~

~~(2) To satisfy the requirement for five hundred hours of supervised work experience, training must be under the supervision of an authorized user at a medical institution and shall include:~~

~~(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 patient or human research subject dosages;~~

~~(d) Using administrative controls to prevent the misadministration of radioactive material;~~

~~(e) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and~~

~~(f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.~~

~~(3) To satisfy the requirement for five hundred hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and must include:~~

~~(a) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~(c) Administering dosages to patients or human research subjects and using syringe radiation shields;~~

~~(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~(e) Patient or human research subject follow-up; or~~

~~c. 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 subdivision b.~~

~~5. **Training for therapeutic use of unsealed radioactive material.** Except as provided in subsection 11, the licensee shall require the authorized user of a radiopharmaceutical listed in section 33-10-07-08 for therapy to be a physician who:~~

~~a. Is certified by:~~

~~(1) The American board of nuclear medicine;~~

~~(2) The American board of radiology in radiology, therapeutic radiology, or radiation oncology;~~

~~(3) Royal college of physicians and surgeons of Canada in nuclear medicine; or~~

~~(4) The American osteopathic board of radiology after 1984; or~~

~~b. Has completed eighty hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.~~

~~(1) To satisfy the requirement for instruction, eighty hours of classroom and laboratory training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

~~(d) Radiation biology;~~

~~(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:~~

~~(a) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;~~

~~(b) Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;~~

~~(c) Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and~~

~~(d) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals.~~

~~6. **Training for therapeutic use of brachytherapy sources.** Except as provided in subsection 11, the licensee shall require the authorized user using a brachytherapy source specified in section 33-10-07-10 for therapy to be a physician who:~~

~~a. Is certified in:~~

~~(1) Radiology, therapeutic radiology, or radiation oncology by the American board of radiology;~~

~~(2) Radiation oncology by the American osteopathic board of radiology;~~

~~(3) Radiology, with a specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or~~

~~(4) Therapeutic radiology by the Canadian royal college of physicians and surgeons; or~~

~~b. Is in the active practice of therapeutic radiology, has completed two hundred hours of instruction in~~

~~basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and five hundred hours of supervised work experience and a minimum of three years of supervised clinical experience.~~

~~(1) To satisfy the requirement for instruction, two hundred hours of classroom and laboratory training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

~~(d) Radiation biology.~~

~~(2) To satisfy the requirement for five hundred hours of supervised work experience, training must be under the supervision of an authorized user at a medical institution and must include:~~

~~(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

~~(b) Checking survey meters for proper operation;~~

~~(c) Preparing, implanting, and removing sealed sources;~~

~~(d) Using administrative controls to prevent the misadministration of radioactive material; and~~

~~(e) Using emergency procedures to control radioactive material.~~

~~(3) To satisfy the requirement for a period of supervised clinical experience, training must include 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. The supervised clinical experience must include:~~

~~(a) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;~~

~~(b) Selecting the proper brachytherapy sources, dose, and method of administration;~~

~~(c) Calculating the dose; and~~

~~(d) Postadministration followup and review of case histories in collaboration with the authorized user.~~

~~7. **Training for ophthalmic use of strontium-90.** Except as provided in subsection 11, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:~~

~~a. Is certified in radiology, therapeutic radiology, or radiation oncology by the American board of radiology; or~~

~~b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed twenty-four hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.~~

~~(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

~~(c) Mathematics pertaining to the use and~~

~~measurement of radioactivity; and~~

~~(d) Radiation biology.~~

~~(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at a medical institution and must include 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) Followup and review of each individual's case history.~~

~~8. **Training for use of sealed sources for diagnosis**. Except as provided in subsection 11, the licensee shall require the authorized user using a sealed source in a device specified in section 33-10-07-09 to be a physician, dentist, or podiatrist who:~~

~~a. Is certified in:~~

~~(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American board of radiology;~~

~~(2) Nuclear medicine by the American board of nuclear medicine;~~

~~(3) Diagnostic radiology or radiology by the American osteopathic board of radiology; or~~

~~(4) Nuclear medicine by the royal college of physicians and surgeons of Canada; or~~

~~b. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for~~

~~instruction, the training must include:~~

~~(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;~~

~~(2) Radiation biology; and~~

~~(3) Radiation protection and training in the use of the device for the purposes authorized by the license.~~

~~9. **Training for teletherapy.** Except as provided in subsection 11, the licensee shall require the authorized user of a sealed source specified in section 33-10-07-11 to be a physician who:~~

~~a. Is certified in:~~

~~(1) Radiology, therapeutic radiology, or radiation oncology by the American board of radiology;~~

~~(2) Radiation oncology by the American osteopathic board of radiology;~~

~~(3) Radiology, with specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or~~

~~(4) Therapeutic radiology by the Canadian royal college of physicians and surgeons; or~~

~~b. Is in the active practice of therapeutic radiology, and has completed two hundred hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, five hundred hours of supervised work experience, and a minimum of three years of supervised clinical experience.~~

~~(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

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

~~(d) Radiation biology.~~

~~(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and shall include:~~

~~(a) Review of the full calibration measurements and periodic spot checks;~~

~~(b) Preparing treatment plans 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 a teletherapy unit or console; and~~

~~(e) Checking and using survey meters.~~

~~(3) To satisfy the requirement for a period of supervised clinical experience, training must include 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. The supervised clinical experience must include:~~

~~(a) Examining individuals and reviewing the individuals' case histories to determine the individuals' suitability for teletherapy treatment, and any limitations or contraindications;~~

~~(b) Selecting the proper dose and how it is to be administered;~~

~~(c) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subject's progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subject's reaction to radiation; and~~

~~(d) Postadministration followup and review of case histories.~~

~~10. **Training for teletherapy physicist.** The licensee shall require the teletherapy physicist to:~~

~~a. Be certified by the American board of radiology in:~~

~~(1) Therapeutic radiological physics;~~

~~(2) Roentgen-ray and gamma-ray physics;~~

~~(3) X-ray and radium physics; or~~

~~(4) Radiological physics; or~~

~~b. Be certified by the American board of medical physics in radiation oncology physics; or~~

~~c. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in subsection 7 of section 33-10-07-05 and subsections 10, 11 and 12 of section 33-10-07-11 under the supervision of a teletherapy physicist during the year of work experience.~~

~~11. **Training for experienced authorized users.** Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a department, United States nuclear regulatory commission, agreement state, or licensing state license on April 1, 1987, who perform only those methods of use for which the practitioners were authorized on that date need not~~

~~comply with the training requirements of this section.~~

12. ~~**Physician training in a three-month program.** A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the accreditation council for graduate medical education and has successfully completed the program, is exempted from the requirements of subsections 3 and 4.~~

13. ~~**Recentness of training.** The training and experience specified in this section shall have been obtained within the five seven years preceding the date of application or the individual shall have had continuing education and applicable experience since the required training and experience was completed.~~

14. ~~**Training for treatment of hyperthyroidism.** Except as provided in subsection 11, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:~~

   a. ~~Eighty 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; and~~

      (4) ~~Radiation biology; and~~

   b. ~~Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.~~

15. ~~**Training for an authorized nuclear pharmacist.** The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:~~

~~a. Has current board certification as a nuclear pharmacist by the board of pharmaceutical specialties, or~~

~~b. (1) Has completed seven hundred hours in a structured educational program consisting of both:~~

~~(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, survey meters, and if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;~~

~~[3] Calculating, assaying, and safely preparing dosages for patients or human research subjects;~~

~~[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~~

~~(2) 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.~~

~~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. The pharmacist who has completed a structured educational program as specified in paragraph 1 of subdivision b of subsection 15 before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (paragraph 2 of subdivision b of subsection 15) and recentness of training (subsection 13) to qualify as an authorized nuclear pharmacist.~~

~~**History:** Effective June 1, 1992; amended effective March 1, 1994; July 1, 1995; May 1, 1998.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

CHAPTER 33-10-07.1
MEDICAL USE OF RADIOACTIVE MATERIAL

Section	
33-10-07.1-01	Purpose and scope
33-10-07.1-02	Definitions
33-10-07.1-03	Maintenance of records
33-10-07.1-04	Provisions for the protection of human research subjects
33-10-07.1-05	Food and drug administration, other federal, and state requirements
33-10-07.1-06	Implementation
33-10-07.1-07	License required
33-10-07.1-08	Application for license, amendment, or renewal
33-10-07.1-09	License amendments
33-10-07.1-10	Notifications
33-10-07.1-11	Exemptions regarding type A specific licenses of broad scope
33-10-07.1-12	License issuance
33-10-07.1-13	Specific exemptions
33-10-07.1-14	Authority and responsibilities for the radiation protection program
33-10-07.1-15	Radiation protection program changes
33-10-07.1-16	Supervision
33-10-07.1-17	Written directives
33-10-07.1-18	Procedures for administrations requiring a written directive
33-10-07.1-19	Suppliers for sealed sources or devices for medical use
33-10-07.1-20	Training for radiation safety officer
33-10-07.1-21	Training for an authorized medical physicist
33-10-07.1-22	Training for an authorized nuclear pharmacist
33-10-07.1-23	Training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist
33-10-07.1-24	Recentness of training
33-10-07.1-25	Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material
33-10-07.1-26	Calibration of survey instruments
33-10-07.1-27	Determination of dosages of unsealed radioactive material for medical use
33-10-07.1-28	Authorization for calibration, transmission, and reference sources
33-10-07.1-29	Requirements for possession of sealed sources and brachytherapy sources

33-10-07.1-30	Labeling of vials and syringes
33-10-07.1-31	Surveys of ambient radiation exposure rate
33-10-07.1-32	Release of individuals containing unsealed radioactive material or implants containing radioactive material
33-10-07.1-33	Provision of mobile medical service
33-10-07.1-34	Decay-in-storage
33-10-07.1-35	Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required
33-10-07.1-36	Training for uptake, dilution, and excretion studies
33-10-07.1-37	Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required
33-10-07.1-38	Permissible molybdenum-99 concentrations
33-10-07.1-39	Permissible aluminum ion concentrations
33-10-07.1-40	Training for imaging and localization studies
33-10-07.1-41	Use of unsealed radioactive material for which a written directive is required
33-10-07.1-42	Safety instruction for the use of unsealed radioactive material for which a written directive is required
33-10-07.1-43	Safety precautions for the use of unsealed radioactive material for which a written directive is required
33-10-07.1-44	Training for use of unsealed radioactive material for which a written directive is required
33-10-07.1-45	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries]
33-10-07.1-46	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]
33-10-07.1-47	Use of sources for manual brachytherapy
33-10-07.1-48	Surveys after source implant and removal
33-10-07.1-49	Brachytherapy sources accountability
33-10-07.1-50	Safety instruction for the use of sources for manual brachytherapy
33-10-07.1-51	Safety precautions for the use of sources for manual brachytherapy
33-10-07.1-52	Calibration measurements of brachytherapy sources

33-10-07.1-53	Decay of strontium-90 sources for ophthalmic treatments
33-10-07.1-54	Therapy-related computer systems
33-10-07.1-55	Training for use of manual brachytherapy sources
33-10-07.1-56	Training for ophthalmic use of strontium-90
33-10-07.1-57	Use of sealed sources for diagnosis
33-10-07.1-58	Training for use of sealed sources for diagnosis
33-10-07.1-59	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit
33-10-07.1-60	Surveys of patients and human research subjects treated with a remote afterloader unit
33-10-07.1-61	Installation, maintenance, adjustment, and repair
33-10-07.1-62	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
33-10-07.1-63	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
33-10-07.1-64	Dosimetry equipment
33-10-07.1-65	Full calibration measurements on teletherapy units
33-10-07.1-66	Full calibration measurements on remote afterloader units
33-10-07.1-67	Full calibration measurements on gamma stereotactic radiosurgery units
33-10-07.1-68	Periodic spot-checks for teletherapy units
33-10-07.1-69	Periodic spot-checks for remote afterloader units
33-10-07.1-70	Periodic spot-checks for gamma stereotactic radiosurgery units
33-10-07.1-71	Additional technical requirements for mobile remote afterloader units
33-10-07.1-72	Radiation surveys
33-10-07.1-73	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units
33-10-07.1-74	Therapy-related computer systems
33-10-07.1-75	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
33-10-07.1-76	Radiation safety officer
33-10-07.1-77	Training for uptake, dilution, and excretion studies
33-10-07.1-78	Training for imaging and localization studies

33-10-07.1-79	Training for therapeutic use of unsealed radioactive material
33-10-07.1-80	Training for treatment of hyperthyroidism
33-10-07.1-81	Training for treatment of thyroid carcinoma
33-10-07.1-82	Training for use of brachytherapy sources
33-10-07.1-83	Training for ophthalmic use of strontium-90
33-10-07.1-84	Training for use of sealed sources for diagnosis
33-10-07.1-85	Training for use of therapeutic medical devices
33-10-07.1-86	Training for an authorized medical physicist
33-10-07.1-87	Training for an authorized nuclear pharmacist
33-10-07.1-88	Training for experienced nuclear pharmacists
33-10-07.1-89	Other medical uses of radioactive material or radiation from radioactive material
33-10-07.1-90	Records of authority and responsibilities for radiation protection programs
33-10-07.1-91	Records of radiation protection program changes
33-10-07.1-92	Records of written directives
33-10-07.1-93	Records for procedures for administrations requiring a written directive
33-10-07.1-94	Records of calibrations of instruments used to measure the activity of unsealed radioactive material
33-10-07.1-95	Records of radiation survey instrument calibrations
33-10-07.1-96	Records of dosages of unsealed radioactive material for medical use
33-10-07.1-97	Records of leak tests and inventory of sealed sources and brachytherapy sources
33-10-07.1-98	Records of surveys for ambient radiation exposure rate
33-10-07.1-99	Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material
33-10-07.1-100	Records of mobile medical services
33-10-07.1-101	Records of decay-in-storage
33-10-07.1-102	Records of molybdenum-99 concentrations
33-10-07.1-103	Records of aluminum ion concentrations
33-10-07.1-104	Records of safety instruction
33-10-07.1-105	Records of surveys after source implant and removal
33-10-07.1-106	Records of brachytherapy source accountability
33-10-07.1-107	Records of calibration measurements of brachytherapy sources
33-10-07.1-108	Records of decay of strontium-90 sources for

	ophthalmic treatments
33-10-07.1-109	Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
33-10-07.1-110	Records of safety procedures
33-10-07.1-111	Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
33-10-07.1-112	Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations
33-10-07.1-113	Records of periodic spot-checks for teletherapy units
33-10-07.1-114	Records of periodic spot-checks for remote afterloader units
33-10-07.1-115	Records of periodic spot-checks for gamma stereotactic radiosurgery units
33-10-07.1-116	Records of additional technical requirements for mobile remote afterloader units
33-10-07.1-117	Records of surveys of therapeutic treatment units
33-10-07.1-118	Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units
33-10-07.1-119	Report and notification of a medical event
33-10-07.1-120	Report and notification of a dose to an embryo, a fetus, or a nursing child
33-10-07.1-121	Report of a leaking source

33-10-07.1-01. Purpose and scope. This chapter contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this chapter are in addition to, and not in substitution for, others in article 33-10. The requirements and provisions of chapters 33-10-01, 33-10-03, 33-10-04.1, 33-10-10, 33-10-11, and 33-10-13 apply to applicants and licensees subject to this chapter unless specifically exempted.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-02. Definitions.

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

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

3. "Authorized medical physicist" means an individual who:

   a. Meets the requirements in subsection 1 of section 33-10-07.1-21 ("training for an authorized medical physicist") and section 33-10-07.1-24 ("recentness of training"); or

   b. Is identified as an authorized medical physicist or teletherapy physicist on:

      (1) A specific medical use license issued by the United States nuclear regulatory commission or an agreement state or a licensing state;

      (2) A medical use permit issued by a United States nuclear regulatory commission master material licensee;

      (3) A permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope medical use licensee; or

      (4) A permit issued by a United States nuclear regulatory commission master material license broad scope medical use permittee.

4. "Authorized nuclear pharmacist" means a pharmacist who:

   a. Meets the requirements in subsection 1 of section 33-10-07.1-22 ("training for an authorized nuclear pharmacist")and section 33-10-07.1-24 ("recentness of training"); or

   b. Is identified as an authorized nuclear pharmacist on:

(1) A specific license issued by the United States nuclear regulatory commission or an agreement state or a licensing state that authorizes medical use or the practice of nuclear pharmacy;

(2) A permit issued by a United States nuclear regulatory commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(3) A permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(4) A permit issued by a United States nuclear regulatory commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with subparagraph d of paragraph 2 of subdivision i of subsection 5 of section 33-10-03-05 or 10 CFR 32.72(b)(4).

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

a. Meets the requirements in section 33-10-07.1-24 ("recentness of training") and subsection 1 of section 33-10-07.1-36 ("training for uptake, dilution, and excretion studies"), subsection 1 of section 33-10-07.1-40 ("training for imaging and localization studies"), subsection 1 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), subsection 1 of section 33-10-07.1-45 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two

hundred twenty megabecquerels [thirty three millicuries]"), subsection 1 of section 33-10-07.1-46 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]"), subsection 1 of section 33-10-07.1-55 ("training for use of manual brachytherapy sources"), subsection 1 of section 33-10-07.1-58 ("training for use of sealed sources for diagnosis"), or subsection 1 of section 33-10-07.1-75 ("training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"); or

b. Is identified as an authorized user on:

(1) A United States nuclear regulatory commission or agreement state or licensing state license that authorizes the medical use of radioactive material;

(2) A permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the medical use of radioactive material;

(3) A permit issued by a United States nuclear regulatory commission or agreement state or licensing state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(4) A permit issued by a United States nuclear regulatory commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

6. "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

7. "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

8. "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with section 33-10-07.1-33 ("provision of mobile medical service").

9. "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.

10. "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

11. "High dose-rate remote afterloader", as used in this chapter, means a brachytherapy device that remotely delivers a dose rate in excess of twelve gray (one thousand two hundred rads) per hour at the point or surface where the dose is prescribed.

12. "Low dose-rate remote afterloader", as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of less than or equal to two gray (two hundred rads) per hour at the point or surface where the dose is prescribed.

13. "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

14. "Manual brachytherapy", as used in this chapter, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

15. "Medical event" means an event that meets the criteria in subsection 1 of section 33-10-07.1-119 ("report and notification of a medical event").

16. "Medical institution" means an organization in which more than one medical discipline is practiced.

17. "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research

subjects under the supervision of an authorized user.

18. "Medium dose-rate remote afterloader", as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of greater than two gray (two hundred rads), but less than twelve gray (one thousand two hundred rads) per hour at the point or surface where the dose is prescribed.

19. "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

20. "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

21. "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

22. "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

23. "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

24. "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

25. "Preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

26. "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

a. In a written directive; or

b. In accordance with the directions of the authorized user for procedures performed pursuant to section 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") and section 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required").

27. "Prescribed dose" means:

a. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

b. For teletherapy, the total dose and dose per fraction as documented in the written directive;

c. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

d. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

28. "Pulsed dose-rate remote afterloader", as used in this chapter, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

a. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

b. Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

29. "Radiation safety officer" means an individual who:

a. Meets the requirements in subsection 1 of section 33-10-07.1-20 ("training for radiation safety officer") and section 33-10-07.1-24 ("recentness of training"); or

b. Is identified as a radiation safety officer on:

(1) A specific medical use license issued by the United States nuclear regulatory commission or an agreement state or a licensing state; or

(2) A medical use permit issued by a United States nuclear regulatory commission master material licensee.

30. "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by the United States nuclear regulatory commission and the agreement states and the licensing states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

31. "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

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

33. "Teletherapy", as used in this chapter, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

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

35. "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

36. "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

37. "Treatment site" means the anatomical description of the

tissue intended to receive a radiation dose, as described in a written directive.

38. "Type of use" means use of radioactive material under sections 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required"), 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required"), 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required"), 33-10-07.1-47 ("use of sources for manual brachytherapy"), 33-10-07.1-57 ("use of sealed sources for diagnosis"), 33-10-07.1-59 ("use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit"), or 33-10-07.1-89 ("other medical uses of radioactive material or radiation from radioactive material").

39. "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

40. "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in section 33-10-07.1-17 ("written directives").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-03. Maintenance of records. Each record required by this chapter must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-04. Provisions for the protection of human research subjects.

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

2. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy for the Protection of Human Subjects, the licensee shall, before conducting research:

   a. Obtain review and approval of the research from an "institutional review board," as defined and described in the Federal Policy for the Protection of Human Subjects; and

   b. Obtain "informed consent," as defined and described in the Federal Policy for the Protection of Human Subjects, from the human research subject.

3. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy for the Protection of Human Subjects, the license shall, before conducting research, apply for and receive a specific amendment to its medical use license from the department. The amendment request must include a written commitment that the licensee will, before conducting research:

   a. Obtain review and approval of the research from an "institutional review board," as defined and described in the Federal Policy for the Protection of Human Subjects; and

   b. Obtain "informed consent", as defined and described in the Federal Policy for the Protection of Human Subjects, from the human research subject.

4. Nothing in this section relieves licensees from complying with the other requirements in this chapter.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-05. Food and drug administration, other federal, and state requirements. Nothing in this chapter relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs or devices.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-06. Implementation.

1. A licensee shall implement the provisions in this chapter on or before [date 6 months from publication of the Final Rule], with the exception of the requirements listed in subsection 2 of this section.

2. A licensee shall implement the training requirements in subsection 1 of section 33-10-07.1-20 ("training for radiation safety officer"), subsection 1 of section 33-10-07.1-21 ("training for an authorized medical physicist"), subsection 1 of section 33-10-07.1-22 ("training for an authorized nuclear pharmacist"), section 33-10-07.1-24 ("recentness of training"), subsection 1 of section 33-10-07.1-36 ("training for uptake, dilution, and excretion studies"), subsection 1 of section 33-10-07.1-40 ("training for imaging and localization studies"), subsection 1 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), subsection 1 of section 33-10-07.1-45 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries]"), subsection 1 of section 33-10-07.1-46 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]"), subsection 1 of section 33-10-07.1-55 ("training for use of manual brachytherapy sources"), subsection 1 of section 33-10-07.1-58

("training for use of sealed sources for diagnosis"), and subsection 1 of section 33-10-07.1-75 ("training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units") on or before October 25, 2004.

3. Prior to October 24, 2004, a licensee shall satisfy the training requirements of this chapter for a radiation safety officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

   a. The appropriate training requirements in sections 33-10-07.1-76 through 33-10-07.1-88; or

   b. The appropriate training requirements in sections 33-10-07.1-14 through 33-10-07.1-24 or sections 33-10-07.1-35 through 33-10-07.1-75.

4. If a license condition exempted a licensee from a provision of this chapter on [insert date 6 months from publication of the Final Rule], then the license condition continues to exempt the licensee from the requirements in the corresponding provision of this chapter.

5. When a requirement in this chapter differs from the requirement in an existing license condition, the requirement in this chapter shall govern.

6. A licensee shall continue to comply with any license condition that requires it to implement procedures required by sections 33-10-07.1-62 ("safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"), 33-10-07.1-68 ("periodic spot-checks for teletherapy units"), 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), and 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units") until there is a license amendment or renewal that modifies the license condition.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-07. License required.

1. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the United States nuclear regulatory commission or an agreement state or a licensing state, or as allowed in subsection 2 of this section.

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

   a. Receives, possesses, uses, or transfers radioactive material in accordance with article 33-10 ("radiological health rules") under the supervision of an authorized user as provided in section 33-10-07.1-16 ("supervision"), unless prohibited by license condition; or

   b. Prepares unsealed radioactive material for medical use in accordance with article 33-10 ("radiological health rules") under the supervision of an authorized nuclear pharmacist or authorized user as provided in section 33-10-07.1-16 ("supervision"), unless prohibited by license condition.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-08. Application for license, amendment, or renewal.

1. An application must be signed by the applicant's or licensee's management.

2. An application for a license for medical use of radioactive material as described in sections 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required"), 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required"), 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required"), 33-10-07.1-47 ("use of sources for manual brachytherapy"), 33-10-07.1-57 ("use of sealed sources for diagnosis"), 33-10-07.1-59 ("use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit"), and 33-10-07.1-89 ("other medical

uses of radioactive material or radiation from radioactive material") must be made by:

a. Filing an application for medical use of radioactive material that includes the facility diagram, equipment, and training and experience qualifications of each radiation safety officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist; and

b. Submitting procedures required by sections 33-10-07.1-62 ("safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"), 33-10-07.1-68 ("periodic spot-checks for teletherapy units"), 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), and 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units"), as applicable.

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

a. Submitting either an application for medical use of radioactive material or a letter requesting the amendment or renewal; and

b. Submitting procedures required by sections 33-10-07.1-62 ("safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"), 33-10-07.1-68 ("periodic spot-checks for teletherapy units"), 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), and 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units"), as applicable.

4. In addition to the requirements in subsections 2 and 3 of this section, an application for a license or amendment for medical use of radioactive material as described in section 33-10-07.1-89 ("other medical uses of radioactive material or radiation from radioactive material") must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in sections 33-10-07.1-01 through 33-10-07.1-34.

a. The applicant shall also provide specific

information on:

(1) Radiation safety precautions and instructions;

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

(3) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

b. The applicant or licensee shall also provide any other information requested by the department in its review of the application.

5. An applicant that satisfies the requirements specified in subdivision b of subsection 4 ("special requirements for specific licenses of broad scope") of section 33-10-03-05 may apply for a type A specific license of broad scope.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-09. License amendments. A licensee shall apply for and must receive a license amendment:

1. Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but that is not authorized on the licensee's current license issued under this chapter;

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

a. For an authorized user, an individual who meets the requirements in section 33-10-07.1-24 ("recentness of training") and subsection 1 of section 33-10-07.1-36 ("training for uptake, dilution, and excretion studies"), subsection 1 of section 33-10-07.1-40 ("training for imaging and localization studies"), subsection 1 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), subsection 1 of section 33-10-07.1-45 ("training

for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries]"), subsection 1 of section 33-10-07.1-46 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]"), subsection 1 of section 33-10-07.1-55 ("training for use of manual brachytherapy sources"), subsection 1 of section 33-10-07.1-58 ("training for use of sealed sources for diagnosis"), subsection 1 of section 33-10-07.1-75 ("training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"), section 33-10-07.1-77 ("training for uptake, dilution, and excretion studies"), section 33-10-07.1-78 ("training for imaging and localization studies"), section 33-10-07.1-79 ("training for therapeutic use of unsealed radioactive material"), section 33-10-07.1-80 ("training for treatment of hyperthyroidism"), section 33-10-07.1-81 ("training for treatment of thyroid carcinoma"), section 33-10-07.1-82 ("training for use of brachytherapy sources"), section 33-10-07.1-83 ("training for ophthalmic use of strontium-90"), section 33-10-07.1-84 ("training for use of sealed sources for diagnosis"), or section 33-10-07.1-85 ("training for use of therapeutic medical devices");

b. For an authorized nuclear pharmacist, an individual who meets the requirements in subsection 1 of section 33-10-07.1-22 ("training for an authorized nuclear pharmacist") or section 33-10-07.1-87 ("training for an authorized nuclear pharmacist") and section 33-10-07.1-24 ("recentness of training");

c. For an authorized medical physicist, an individual who meets the requirements in subsection 1 of section 33-10-07.1-21 ("training for an authorized medical physicist") or section 33-10-07.1-86 ("training for an authorized medical physicist") and section 33-10-07.1-24 ("recentness of training");

d. An individual who is identified as an authorized

user, an authorized nuclear pharmacist, or authorized medical physicist:

(1) On a United States nuclear regulatory commission or agreement state or licensing state license or other equivalent permit or license recognized by the department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) On a permit issued by a United States nuclear regulatory commission or agreement state or licensing state specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(3) On a permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

3. Before it changes radiation safety officers, except as provided in subsection 3 of section 33-10-07.1-14 ("authority and responsibilities for the radiation protection program");

4. Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

5. Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either section 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") or section 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required");

6. Before it changes an address of use identified in the

application or on the license; and

7. Before it revises procedures required by sections 33-10-07.1-62 ("safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units"), 33-10-07.1-68 ("periodic spot-checks for teletherapy units"), 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), and 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units"), as applicable, where such revision reduces radiation safety.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-10. Notifications.

1. A licensee shall provide the department a copy of the board certification, the United States nuclear regulatory commission or agreement state or licensing state license, the permit issued by a United States nuclear regulatory commission master material licensee, the permit issued by a United States nuclear regulatory commission or agreement state or licensing state licensee of broad scope, or the permit issued by a United States nuclear regulatory commission master material license broad scope permittee for each individual no later than thirty days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under subsection 2 of section 33-10-07.1-09 ("license amendments").

2. A licensee shall notify the department by letter no later than thirty days after:

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

   b. The licensee's mailing address changes;

   c. The licensee's name changes, but the name change does not constitute a transfer of control of the

license as described in subdivision b of subsection 7 ("specific terms and conditions of licenses") of section 33-10-03-05; or

d. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either section 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") or section 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required").

3. The licensee shall mail the documents required in this section to the department at the address identified in section 33-10-01-13 ("communications").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-11. Exemptions regarding type A specific licenses of broad scope. A licensee possessing a type A specific license of broad scope for medical use, issued under subsection 4 ("special requirements for specific licenses of broad scope") of section 33-10-03-05, is exempt from:

1. The provisions of subsection 4 of section 33-10-07.1-08 ("application for license, amendment, or renewal") regarding the need to file an amendment to the license for medical use of radioactive material, as described in section 33-10-07.1-89 ("other medical uses of radioactive material or radiation from radioactive material");

2. The provisions of subsection 2 of section 33-10-07.1-09 ("license amendments");

3. The provisions of subsection 5 of section 33-10-07.1-09 ("license amendments") regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

4. The provisions of subsection 1 of section 33-10-07.1-10 ("notifications");

5. The provisions of subdivision a of subsection 2 of section 33-10-07.1-10 ("notifications") for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

6. The provisions of subdivision d of subsection 2 of section 33-10-07.1-10 ("notifications") regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either section 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") or section 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required").

7. The provisions of subsection 1 of section 33-10-07.1-19 ("suppliers for sealed sources or devices for medical use").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-12. License issuance.

1. The department shall issue a license for the medical use of radioactive material if:

   a. The applicant has filed an application for medical use of radioactive material in accordance with the instructions in section 33-10-07.1-08 ("application for license, amendment, or renewal");

   b. The applicant has paid any applicable fee as provided in chapter 33-10-11 ("fees for issuance of license and registration certificates and inspections");

   c. The department finds the applicant equipped and committed to observe the safety standards established by the department in article 33-10 ("radiological health rules") for the protection of the public health and safety; and

   d. The applicant meets the requirements of chapter 33-

10-03 ("licensing of radioactive material").

2. The department shall issue a license for mobile medical service if the applicant:

   a. Meets the requirements in subsection 1 of this section; and

   b. Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-13. Specific exemptions. The department may, upon application of any interested person or upon its own initiative, grant exemptions from the rules in this chapter that it determines are authorized by law, will not endanger life or property or the common defense and security and are otherwise in the public interest.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-14. Authority and responsibilities for the radiation protection program.

1. In addition to the radiation protection program requirements of section 33-10-04.1-05 ("radiation protection programs"), a licensee's management shall approve in writing:

   a. Requests for a license application, renewal, or amendment before submittal to the department;

   b. Any individual before allowing that individual to work as an authorized user, authorized nuclear

pharmacist, or authorized medical physicist; and

c. Radiation protection program changes that do not require a license amendment and are permitted under section 33-10-07.1-15 ("radiation protection program changes");

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

3. For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer, under sections 33-10-07.1-20 ("training for radiation safety officer") and 33-10-07.1-24 ("recentness of training"), to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in subsection 7 of this section, if the licensee takes the actions required in subsections 2, 5, 7, and 8 of this section and notifies the department in accordance with subsection 2 of section 33-10-07.1-10 ("notifications").

4. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with subsection 3 of this section, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

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

6. Licensees that are authorized for two or more different types of uses of radioactive material under sections 33-10-07.1-41 through 33-10-07.1-56 and sections 33-10-07.1-59 through 33-10-07.1-75, or two or more types of units under sections 33-10-07.1-59 through 33-10-07.1-75, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The radiation safety committee must include an authorized user of each type of use permitted by the license, the

radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The radiation safety committee may include other members the licensee considers appropriate.

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

   a. Identify radiation safety problems;

   b. Initiate, recommend, or provide corrective actions;

   c. Stop unsafe operations; and,

   d. Verify implementation of corrective actions.

8. A licensee shall retain a record of actions taken under subsections 1, 2, and 5 of this section in accordance with section 33-10-07.1-90 ("records of authority and responsibilities for radiation protection programs").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-15. Radiation protection program changes.

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

   a. The revision does not require a license amendment under section 33-10-07.1-09 ("license amendments");

   b. The revision is in compliance with article 33-10 ("radiological health rules") and the license;

   c. The revision has been reviewed and approved by the radiation safety officer and licensee management; and

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

2. A licensee shall retain a record of each change in accordance with section 33-10-07.1-91 ("records of

radiation protection program changes").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-16. Supervision.

1. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by subdivision a of subsection 2 of section 33-10-07.1-07 ("license required"), shall:

   a. In addition to the requirements in subsection 2 ("instructions to workers") of section 33-10-10-02, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules in article 33-10 ("radiological health rules"), and license conditions with respect to the use of radioactive material; and

   b. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules in article 33-10 ("radiological health rules"), and license conditions with respect to the medical use of radioactive material.

2. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by subdivision b of subsection 2 of section 33-10-07.1-07 ("license required"), shall:

   a. In addition to the requirements in subsection 2 ("instructions to workers") of section 33-10-10-02, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

   b. Require the supervised individual to follow the

instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules in article 33-10 ("radiological health rules"), and license conditions.

3. A licensee that permits supervised activities under subsections 1 and 2 of this section is responsible for the acts and omissions of the supervised individual.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-17. Written directives.

1. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than one thousand one hundred ten kilobecquerels [thirty microcuries], any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

   a. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty eight hours of the oral directive.

2. The written directive must contain the patient or human research subject's name and the following information:

   a. For any administration of quantities greater than one thousand one hundred ten kilobecquerels [thirty microcuries] of sodium iodide I-131: the dosage;

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

   c. For gamma stereotactic radiosurgery: the total

dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

d. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

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

f. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

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

(2) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

3. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

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

4. The licensee shall retain a copy of the written directive in accordance with section 33-10-07.1-92 ("records of written directives").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-18. Procedures for administrations requiring a written directive.

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

   a. The patient's or human research subject's identity is verified before each administration; and

   b. Each administration is in accordance with the written directive.

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

   a. Verifying the identity of the patient or human research subject;

   b. Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

   c. Checking both manual and computer-generated dose calculations; and

   d. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by section 33-10-07.1-59 ("use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit").

3. A licensee shall retain a copy of the procedures required under subsection 1 of this section in accordance with section 33-10-07.1-93 ("records for procedures for administrations requiring a written directive").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-19. Suppliers for sealed sources or devices for medical use. For medical use, a licensee may only use:

1. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under chapter 33-10-03 ("licensing of radioactive material") and subdivision j ("manufacture and distribution of sources or devices containing radioactive material for medical use") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state;

2. Sealed sources or devices noncommercially transferred from a chapter 33-10-07.1 licensee; or

3. Teletherapy sources manufactured and distributed in accordance with a license issued under chapter 33-10-03 ("licensing of radioactive material") or the equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-20. Training for radiation safety officer. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in section 33-10-07.1-14 ("authority and responsibilities for the radiation protection program") to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

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

   (1) Two hundred hours of didactic training in the following areas:

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

(d) Radiation biology; and

(e) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a United States nuclear regulatory commission or agreement state or licensing state license or permit issued by a United States nuclear regulatory commission master material licensee that authorizes similar type of use of radioactive material involving the following:

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

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

(c) Securing and controlling radioactive material;

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

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

(f) Using emergency procedures to control radioactive material; and

(g) Disposing of radioactive material; and

b. Has obtained written certification, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the structured educational program requirements in subdivision a of subsection 2 of this section and

has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or

3. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-21. Training for an authorized medical physicist. Except as provided in section 33-10-07.1-23 ("training for an experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized medical physicist to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in sections 33-10-07.1-29 ("requirements for possession of sealed sources and brachytherapy sources"), 33-10-07.1-53 ("decay of strontium-90 sources for ophthalmic treatments"), 33-10-07.1-65 ("full calibration measurements on teletherapy units"), 33-10-07.1-66 ("full calibration measurements on remote afterloader units"), 33-10-07.1-67 ("full calibration measurements on gamma stereotactic radiosurgery units"), 33-10-07.1-68 ("periodic spot-checks for

teletherapy units"), 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units"), and 33-10-07.1-72 ("radiation surveys"), as applicable; and

b. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in section 33-10-07.1-21 ("training for an authorized medical physicist") or equivalent United States nuclear regulatory commission or agreement state or licensing state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-22. Training for an authorized nuclear pharmacist. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

1. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed seven hundred hours in a structured educational program consisting of both:

(1) Didactic training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

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

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid medical events in the administration of radioactive material; and

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

b. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-23. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

1. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a United States nuclear regulatory commission or agreement state or licensing state license or a permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope licensee or master material license permit or by a master material license permittee of broad scope before [insert date 6 months from publication of the Final Rule] need not comply with the training requirements of sections 33-10-07.1-20 ("training for radiation safety officer"), 33-10-07.1-21 ("training for an authorized medical physicist"), or 33-10-07.1-22 ("training for an authorized nuclear pharmacist"), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the United States nuclear regulatory commission or an agreement state or a licensing state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee before [insert date 6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements in sections 33-10-07.1-35 through 33-10-07.1-75.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-24. Recentness of training. The training and experience specified in chapter 33-10-07.1 ("medical use of radioactive material") must have been obtained within the 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.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-25. Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material.

1. For direct measurements performed in accordance with section 33-10-07.1-27 ("determination of dosages of unsealed radioactive material for medical use"), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

2. A licensee shall calibrate the instrumentation required in subsection 1 of this section in accordance with nationally recognized standards or the manufacturer's instructions.

3. A licensee shall retain a record of each instrument calibration required by this section in accordance with section 33-10-07.1-94 ("records of calibrations of instruments used to measure the activity of unsealed radioactive material").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-26. Calibration of survey instruments.

1. A licensee shall calibrate the survey instruments used to show compliance with chapter 33-10-07.1 ("medical use of radioactive material") and chapter 33-10-04.1 ("standards for protection against radiation") before first use, annually, and following a repair that affects the calibration. A licensee shall:

   a. Calibrate all scales with readings up to ten millisieverts [one thousand millirems] per hour with a radiation source;

   b. Calibrate two separated readings on each scale or

decade that will be used to show compliance; and

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

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

3. A licensee shall retain a record of each survey instrument calibration in accordance with section 33-10-07.1-95 ("records of radiation survey instrument calibrations").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-27. Determination of dosages of unsealed radioactive material for medical use.

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

2. For a unit dosage, this determination must be made by:

a. Direct measurement of radioactivity; or

b. A decay correction, based on the activity or activity concentration determined by:

(1) A manufacturer or preparer licensed under subdivision i ("manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 33-10-07.1") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state; or

(2) A United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the United States food

and drug administration.

3. For other than unit dosages, this determination must be made by:

   a. Direct measurement of radioactivity;

   b. Combination of measurement of radioactivity and mathematical calculations; or

   c. Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under subdivision i ("manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 33-10-07.1") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state.

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

5. A licensee shall retain a record of the dosage determination required by this section in accordance with section 33-10-07.1-96 ("records of dosages of unsealed radioactive material for medical use").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-28. Authorization for calibration, transmission, and reference sources. Any person authorized by section 33-10-07.1-07 ("license required") for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

1. Sealed sources, not exceeding one thousand one hundred ten megabecquerels [thirty millicuries] each, manufactured and distributed by a person licensed under subdivision j ("manufacture and distribution of sources

or devices containing radioactive material for medical use") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state.

2. Sealed sources, not exceeding one thousand one hundred ten megabecquerels [thirty millicuries] each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under subdivision j ("manufacture and distribution of sources or devices containing radioactive material for medical use") of subsection 5 of section 33-10-03-05, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

3. Any radioactive material with a half-life not longer than one hundred twenty days in individual amounts not to exceed five hundred sixty megabecquerels [fifteen millicuries].

4. Any radioactive material with a half-life longer than one hundred twenty days in individual amounts not to exceed the smaller of seven thousand four hundred kilobecquerels [two hundred microcuries] or one thousand times the quantities in schedule F ("criteria related to financial assurance and decommissioning") of chapter 33-10-03.

5. Technetium-99m in amounts as needed.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-29. Requirements for possession of sealed sources and brachytherapy sources.

1. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

2. A licensee in possession of a sealed source shall:

   a. Test the source for leakage before its first use unless the licensee has a certificate from the

supplier indicating that the source was tested within six months before transfer to the licensee; and

b. Test the source for leakage at intervals not to exceed six months or at other intervals approved by the United States nuclear regulatory commission or an agreement state or a licensing state in the Sealed Source and Device Registry.

3. To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of one hundred eighty five becquerels [five-thousandths microcurie] of radioactive material in the sample.

4. A licensee shall retain leak test records in accordance with subsection 1 of section 33-10-07.1-97 ("records of leak tests and inventory of sealed sources and brachytherapy sources").

5. If the leak test reveals the presence of one hundred eighty five becquerels [five-thousandths microcurie] or more of removable contamination, the licensee shall:

a. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in chapters 33-10-03 ("licensing of radioactive material") and 33-10-04.1 ("standards for protection against radiation"); and

b. File a report within five days of the leak test in accordance with section 33-10-07.1-121 ("report of a leaking source").

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

a. Sources containing only radioactive material with a half-life of less than thirty days;

b. Sources containing only radioactive material as a gas;

c. Sources containing three thousand seven hundred kilobecquerels [one hundred microcuries] or less of beta-emitting or gamma-emitting material or three

hundred seventy kilobecquerels [ten microcuries] or less of alpha-emitting material;

d. Seeds of iridium-192 encased in nylon ribbon; and

e. Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.

7. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with subsection 2 of section 33-10-07.1-97 ("records of leak tests and inventory of sealed sources and brachytherapy sources").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-30. Labeling of vials and syringes. Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-31. Surveys of ambient radiation exposure rate.

1. In addition to the surveys required by chapter 33-10-04.1 ("standards for protection against radiation"), a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

2. A licensee does not need to perform the surveys required by subsection 1 of this section in an area where patients

or human research subjects are confined when they cannot be released under section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material").

3. A licensee shall retain a record of each survey in accordance with section 33-10-07.1-98 ("records of surveys for ambient radiation exposure rate").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-32. Release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts [five hundred millirem]. (United States nuclear regulatory commission publication NUREG-1556, volume 9, "consolidated guidance about material licenses: program-specific guidance about medical use licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five millisieverts.)

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

   a. Guidance on the interruption or discontinuation of breast-feeding; and

   b. Information on the potential consequences, if any, of failure to follow the guidance.

3. A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with subsection 1 of section 33-10-07.1-99 ("records of the release of individuals containing unsealed radioactive material or implants containing radioactive material").

4. The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with subsection 2 of section 33-10-07.1-99 ("records of the release of individuals containing unsealed radioactive material or implants containing radioactive material").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-33. Provision of mobile medical service.

1. A licensee providing mobile medical service shall:

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

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

   c. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

   d. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in chapter 33-10-04.1 ("standards for protection against radiation").

2. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material.

Radioactive material delivered to the client must be received and handled in conformance with the client's license.

3. A licensee providing mobile medical services shall retain the letter required in subdivision a of subsection 1 and the record of each survey required in subdivision d of subsection 1 of this section in accordance with subsections 1 and 2 of section 33-10-07.1-100 ("records of mobile medical services"), respectively.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-34. Decay-in-storage.

1. A licensee may hold radioactive material with a physical half-life of less than one hundred twenty days for decay-in-storage before disposal without regard to its radioactivity if it:

   a. Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

   b. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

2. A licensee shall retain a record of each disposal permitted under subsection 1 of this section in accordance with section 33-10-07.1-101 ("records of decay-in-storage").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-35. Use of unsealed radioactive material for

uptake, dilution, and excretion studies for which a written directive is not required. Except for quantities that require a written directive under subsection 2 of section 33-10-07.1-17 ("written directives"), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

1. Obtained from a manufacturer or preparer licensed under subdivision i ("manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 33-10-07.1") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state; or

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in sections 33-10-07.1-40 ("training for imaging and localization studies") or section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), or an individual under the supervision of either as specified in section 33-10-07.1-16 ("supervision"); or

3. Obtained from and prepared by a United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the United States food and drug administration; or

4. Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the United States food and drug administration.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-36. Training for uptake, dilution, and excretion studies. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an authorized user of unsealed radioactive material

for the uses authorized under section 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. Is an authorized user under sections 33-10-07.1-40 ("training for imaging and localization studies") or 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required") or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state; or

3. a. Has completed sixty hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

   (1) Classroom and laboratory training in the following areas:

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

      (d) Chemistry of radioactive material for medical use; and

      (e) Radiation biology; and

   (2) Work experience, under the supervision of an authorized user who meets the requirements in section 33-10-07.1-36 ("training for uptake, dilution, and excretion studies"), section 33-10-07.1-40 ("training for imaging and localization studies"), or section 33-10-07.1-44 ("training for use of unsealed radioactive

material for which a written directive is required") or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

b. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in section 33-10-07.1-36 ("training for uptake, dilution, and excretion studies"), section 33-10-07.1-40 ("training for imaging and localization studies"), or section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required") or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state, that the individual has satisfactorily completed the requirements in subdivision a of subsection 3 of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under section 33-10-07.1-35 ("use of unsealed radioactive material for

uptake, dilution, and excretion studies for which a written directive is not required").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-37. Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required. Except for quantities that require a written directive under subsection 2 of section 33-10-07.1-17 ("written directives"), a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

1. Obtained from a manufacturer or preparer licensed under subdivision i ("manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 33-10-07.1") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in sections 33-10-07.1-40 ("training for imaging and localization studies") or 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), or an individual under the supervision of either as specified in section 33-10-07.1-16 ("supervision");

3. Obtained from and prepared by a United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the United States food and drug administration; or

4. Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the United States food and drug administration.

History:

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-38. Permissible molybdenum-99 concentrations.

1. A licensee may not administer to humans a radiopharmaceutical that contains more than one hundred fifty becquerels of molybdenum-99 per megabecquerel of technetium-99m [fifteen-hundredths microcurie of molybdenum-99 per millicurie of technetium-99m].

2. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection 1 of this section.

3. If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with section 33-10-07.1-102 ("records of molybdenum-99 concentrations").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-39. Permissible aluminum ion concentrations.

1. A licensee may not administer to humans a radiopharmaceutical that contains more than ten micrograms of aluminum per milliliter of technetium-99m.

2. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the aluminum ion concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection 1 of this section.

3. If a licensee is required to measure the aluminum ion concentration, the licensee shall retain a record of each measurement in accordance with section 33-10-07.1-103 ("records of aluminum ion concentrations").

History:

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-40. Training for imaging and localization studies. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under section 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required") to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. Is an authorized user under section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required") or equivalent requirements of the United States nuclear regulatory commmission, an agreement state, or a licensing state; or

3. a. Has completed seven hundred hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum,:

   (1) Classroom and laboratory training in the following areas:

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

      (d) Chemistry of radioactive material for medical use;

      (e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user, who meets the requirements in sections 33-10-07.1-40 ("training for imaging and localization studies") or 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required") or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

b. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in sections 33-10-07.1-40 ("training for imaging and localization studies") or 33-10-

07.1-44 ("training for use of unsealed radioactive material for which a written directive is required") or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, that the individual has satisfactorily completed the requirements in subdivision a of subsection 3 of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under sections 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") and 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-41. Use of unsealed radioactive material for which a written directive is required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

1. Obtained from a manufacturer or preparer licensed under subdivision i ("manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 33-10-07.1") of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in sections 33-10-07.1-40 ("training for imaging and localization studies") or 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), or an individual under the supervision of either as specified in section 33-10-07.1-16 ("supervision"); or

3. Obtained from and prepared by a United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with an

investigational new drug protocol accepted by the United States food and drug administration; or

4. Prepared by the licensee for use in research in accordance with an investigational new drug protocol accepted by the United States food and drug administration.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-42. Safety instruction for the use of unsealed radioactive material for which a written directive is required. In addition to the requirements of subsection 2 ("instructions to workers") of section 33-10-10-02:

1. A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"). To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

   a. Patient or human research subject control;

   b. Visitor control, including:

      (1) Routine visitation to hospitalized individuals in accordance with paragraph 1 of subdivision a of subsection 1 of section 33-10-04.1-07 ("radiation dose limits for individual members of the public"); and

      (2) Visitation authorized in accordance with subdivision c of subsection 1 of section 33-10-04.1-07 ("radiation dose limits for individual members of the public");

   c. Contamination control;

   d. Waste control; and

   e. Notification of the radiation safety officer, or his or her designee, and the authorized user if the

patient or the human research subject has a medical emergency or dies.

2. A licensee shall retain a record of individuals receiving instruction in accordance with section 33-10-07.1-104 ("records of safety instruction").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-43. Safety precautions for the use of unsealed radioactive material for which a written directive is required.

1. For each patient or human research subject who cannot be released under section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"), a licensee shall:

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

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

      (2) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material");

   b. Visibly post the patient's or the human research subject's room with a "radioactive materials" sign.

   c. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

   d. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument

set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

2. A licensee shall notify the radiation safety officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-44. Training for use of unsealed radioactive material for which a written directive is required. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under section 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required") to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed seven hundred hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

   (1) Classroom and laboratory training in the following areas:

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

      (d) Chemistry of radioactive material for

medical use; and

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in subsections 1 or 2 of this section, or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A supervising authorized user, who meets the requirements in subsection 2 of this section, must have experience in administering dosages in the same dosage category or categories (i.e., items 1, 2, 3, or 4 of subparagraph g of this paragraph) as the individual requesting authorized user status. The work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(f) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(g) Administering dosages of radioactive drugs to patients or human research

subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

[1] Oral administration of less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131;

[2] Oral administration of greater than one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131; (Note: experience with at least three of these cases also satisfies the requirement in item 1 for oral administration of less than or equal to one thousand two hundred twenty megabecquerels.)

[3] Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than one hundred fifty kilo electron volts; and

[4] Parenteral administration of any other radionuclide; and

b. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under section 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required"). The written certification must be signed by a preceptor authorized user who meets the requirements in subsections 1 or 2 of this section (33-10-07.1-44), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. The preceptor authorized user, who meets the requirements in subsection 2 of this section, must have experience in administering dosages in the same dosage category or categories (i.e., items 1,

2, 3, or 4 of subparagraph g of paragraph 2 of subdivision a of subsection 2 of this section) as the individual requesting authorized user status.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-45. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries]. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries], to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. Is an authorized user under subsections 1 or 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"); is an authorized user for the oral administration of sodium iodide I-131 requiring a written directive; is an authorized user under section 33-10-07.1-46 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]"); or is an authorized user under equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

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

   (1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology; and

b. Has work experience, under the supervision of an authorized user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), this section (33-10-07.1-45), section 33-10-07.1-46 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]"), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A supervising authorized user who meets the requirements in subsection 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), must have experience in oral administration of sodium iodide I-131 requiring a written directive. The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

(5) Using procedures to contain spilled radioactive material safely and using proper

decontamination procedures; and

(6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131; and

c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 3 of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under section 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required"). The written certification must be signed by a preceptor authorized user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), this section (33-10-07.1-45), section 33-10-07.1-46 ("training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]"), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A preceptor authorized user, who meets the requirements in subsection 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), must have experience in oral administration of sodium iodide I-131 requiring a written directive.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-46. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries]. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the

licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [thirty three millicuries], to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. Is an authorized user under subsection 1 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"); subsection 2 of section 33-10-07.1-44 for the oral administration of greater than one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131 requiring a written directive; or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

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

   (1) Radiation physics and instrumentation;

   (2) Radiation protection;

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

   (4) Chemistry of radioactive material for medical use; and

   (5) Radiation biology; and

   b. Has work experience, under the supervision of an authorized user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), this section (33-10-07.1-46), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A

supervising authorized user, who meets the requirements in subsection 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), must have experience in the oral administration of greater than one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131 requiring a written directive. The work experience must involve:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

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

(6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131; and

c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 3 of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under section 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required"). The written certification must be signed by a preceptor authorized user who meets the requirements in subsections 1 or 2 of section 33-

10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), this section (33-10-07.1-46), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A preceptor authorized user, who meets the requirements in subsection 2 of section 33-10-07.1-44 ("training for use of unsealed radioactive material for which a written directive is required"), must have experience in oral administration of greater than one thousand two hundred twenty megabecquerels [thirty three millicuries] of sodium iodide I-131 requiring a written directive.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-47. Use of sources for manual brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of subsection 1 of section 33-10-07.1-19 ("suppliers for sealed sources or devices for medical use") are met.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-48. Surveys after source implant and removal.

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

2. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human

research subject with a radiation detection survey instrument to confirm that all sources have been removed.

3. A licensee shall retain a record of the surveys required by subsections 1 and 2 of this section in accordance with section 33-10-07.1-105 ("records of surveys after source implant and removal").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-49. Brachytherapy sources accountability.

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

2. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

3. A licensee shall maintain a record of the brachytherapy source accountability in accordance with section 33-10-07.1-106 ("records of brachytherapy source accountability").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-50. Safety instruction for the use of sources for manual brachytherapy. In addition to the requirements of subsection 2 ("instructions to workers") of section 33-10-10-02:

1. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"). To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the:

   a. Size and appearance of the brachytherapy sources;

b. Safe handling and shielding instructions;

c. Patient or human research subject control;

d. Visitor control, including both:

(1) Routine visitation of hospitalized individuals in accordance with paragraph 1 of subdivision a of subsection 1 of section 33-10-04.1-07 ("radiation dose limits for individual members of the public"); and

(2) Visitation authorized in accordance with subdivision c of subsection 1 of section 33-10-04.1-07 ("radiation dose limits for individual members of the public"); and

e. Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

2. A licensee shall retain a record of individuals receiving instruction in accordance with section 33-10-07.1-104 ("records of safety instruction").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-51. Safety precautions for the use of sources for manual brachytherapy.

1. For each patient or human research subject who is receiving brachytherapy and cannot be released under section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"), a licensee shall:

a. Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

b. Visibly post the patient's or human research subject's room with a "radioactive materials" sign; and

c. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

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

a. Dislodged from the patient; and

b. Lodged within the patient following removal of the source applicators.

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

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-52. Calibration measurements of brachytherapy sources.

1. Before the first medical use of a brachytherapy source on or after [insert date 6 months from publication of the Final Rule], a licensee shall have:

a. Determined the source output or activity using a dosimetry system that meets the requirements of subsection 1 of section 33-10-07.1-64 ("dosimetry equipment");

b. Determined source positioning accuracy within applicators; and

c. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subdivisions a and b of subsection 1 of this section.

2. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the american association of physicists in medicine that are made in accordance with subsection 1 of this section.

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

4. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-107 ("records of calibration measurements of brachytherapy sources").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-53. Decay of strontium-90 sources for ophthalmic treatments.

1. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under section 33-10-07.1-52 ("calibration measurements of brachytherapy sources").

2. A licensee shall retain a record of the activity of each strontium-90 source in accordance with section 33-10-07.1-108 ("records of decay of strontium-90 sources for ophthalmic treatments").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-54. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays; and

4. The accuracy of the software used to determine sealed source positions from radiographic images.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-55. Training for use of manual brachytherapy sources. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under section 33-10-07.1-47 ("use of sources for manual brachytherapy") to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

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

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

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

      (d) Radiation biology; and

   (2) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in section 33-10-07.1-55 ("training for use of manual brachytherapy sources") or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state at a

medical institution, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a medical event involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material; and

b. Has obtained three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in section 33-10-07.1-55 ("training for use of manual brachytherapy sources") or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state, as part of a formal training program approved by the residency review committee for radiation oncology of the accreditation council for graduate medical education or the committee on postdoctoral training of the american osteopathic association. This experience may be obtained concurrently with the supervised work experience required by paragraph 2 of subdivision a of subsection 2 of this section; and

c. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in section 33-10-07.1-55 ("training for use of manual brachytherapy sources") or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state, that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 2 of this

section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under section 33-10-07.1-47 ("use of sources for manual brachytherapy").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-56. Training for ophthalmic use of strontium-90. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

1. Is an authorized user under section 33-10-07.1-55 ("training for use of manual brachytherapy sources") or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

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

   (1) Radiation physics and instrumentation;

   (2) Radiation protection;

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

   (4) Radiation biology; and

   b. 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. This supervised clinical training must involve:

   (1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Follow up and review of each individual's case history; and

c. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in section 33-10-07.1-55 ("training for use of manual brachytherapy sources"), this section (33-10-07.1-56), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, that the individual has satisfactorily completed the requirements in subsections 1 and 2 of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-57. Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-58. Training for use of sealed sources for diagnosis. Except as provided in section 33-10-07.1-23 ("training

for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under section 33-10-07.1-57 ("use of sealed sources for diagnosis") to be a physician, dentist, or podiatrist who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

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

   a. Radiation physics and instrumentation;

   b. Radiation protection;

   c. Mathematics pertaining to the use and measurement of radioactivity;

   d. Radiation biology; and

   e. Training in the use of the device for the uses requested.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-59. Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of subsection 1 of section 33-10-07.1-19 ("suppliers for sealed sources or devices for medical use") are met.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-60. Surveys of patients and human research subjects treated with a remote afterloader unit.

1. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that each source has been removed from the patient or human research subject and returned to the safe shielded position.

2. A licensee shall retain a record of these surveys in accordance with section 33-10-07.1-105 ("records of surveys after source implant and removal").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-61. Installation, maintenance, adjustment, and repair.

1. Only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of the unit or a source.

2. Except for low dose-rate remote afterloader units, only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

3. For a low dose-rate remote afterloader unit, only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source

contained in the unit.

4. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with section 33-10-07.1-109 ("records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-62. Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. A licensee shall:

   a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

   b. Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with a source;

   c. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

   d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place a source in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

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

      (2) The process for restricting access to and posting of the treatment area to minimize the

risk of inadvertent exposure; and

(3) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

2. A copy of the procedures required by subdivision d of subsection 1 of this section must be physically located at the unit console.

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

   a. The location of the procedures required by subdivision d of subsection 1 of this section; and

   b. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

4. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

   a. The procedures identified in subdivision d of subsection 1 of this section; and

   b. The operating procedures for the unit.

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

6. A licensee shall retain a record of individuals receiving instruction required by subsection 4 of this section, in accordance with section 33-10-07.1-104 ("records of safety instruction").

7. A licensee shall retain a copy of the procedures required by subdivision d of subsection 1 of this section and subdivision b of subsection 4 of this section in accordance with section 33-10-07.1-110 ("records of safety procedures").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-63. Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

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

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

   a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

   b. Cause each source to be shielded when an entrance door is opened; and

   c. Prevent any source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

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

4. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

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

6. In addition to the requirements specified in subsections 1 through 5 of this section, a licensee shall:

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

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

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

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

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

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

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

d. Notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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

a. Remaining in the unshielded position; or

b. Lodged within the patient following completion of the treatment.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-64. Dosimetry equipment.

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

   a. The system must have been calibrated using a system or source traceable to the national institute of science and technology and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the american association of physicists in medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

   b. The system must have been calibrated within the previous four years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past twenty four months by the national institute of science and technology or by a calibration laboratory accredited by the american association of physicists in medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

2. The licensee shall have a dosimetry system available for

use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection 1 of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection 1 of this section.

3. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with section 33-10-07.1-111 ("records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-65. Full calibration measurements on teletherapy units.

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

   a. Before the first medical use of the unit; and

   b. Before medical use under the following conditions:

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

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

      (3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

   c. At intervals not exceeding one year.

2. To satisfy the requirement of subsection 1 of this section, full calibration measurements must include determination of:

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

   b. The coincidence of the radiation field and the field indicated by the light beam localizing device;

   c. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

   d. Timer accuracy and linearity over the range of use;

   e. On-off error; and

   f. The accuracy of all distance measuring and localization devices in medical use.

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 ("dosimetry equipment") to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision a of subsection 2 of this section may be made using a dosimetry system that indicates relative dose rates.

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

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

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

7. A licensee shall retain a record of each calibration in

accordance with section 33-10-07.1-112 ("records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-66. Full calibration measurements on remote afterloader units.

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

   a. Before the first medical use of the unit;

   b. Before medical use under the following conditions:

      (1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

      (2) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

      (3) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy five days; and

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

2. To satisfy the requirement of subsection 1 of this section, full calibration measurements must include, as applicable, determination of:

   a. The output within plus or minus five percent;

   b. Source positioning accuracy to within plus or minus one millimeter;

   c. Source retraction with backup battery upon power

failure;

d. Length of the source transfer tubes;

e. Timer accuracy and linearity over the typical range of use;

f. Length of the applicators; and

g. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 ("dosimetry equipment") to measure the output.

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

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

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

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

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

9. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-112 ("records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations").

History:

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-67. Full calibration measurements on gamma stereotactic radiosurgery units.

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

   a. Before the first medical use of the unit;

   b. Before medical use under the following conditions:

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

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

      (3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

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

2. To satisfy the requirement of subsection 1 of this section, full calibration measurements must include determination of:

   a. The output within plus or minus three percent;

   b. Relative helmet factors;

   c. Isocenter coincidence;

   d. Timer accuracy and linearity over the range of use;

e. On-off error;

f. Trunnion centricity;

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

h. Helmet microswitches;

i. Emergency timing circuits; and

j. Stereotactic frames and localizing devices (trunnions).

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 ("dosimetry equipment") to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision a of subsection 2 of this section may be made using a dosimetry system that indicates relative dose rates.

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

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

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

7. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-112 ("records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-68. Periodic spot-checks for teletherapy units.

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

   a. Timer accuracy, and timer linearity over the range of use;

   b. On-off error;

   c. The coincidence of the radiation field and the field indicated by the light beam localizing device;

   d. The accuracy of all distance measuring and localization devices used for medical use;

   e. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 2 of section 33-10-07.1-64 ("dosimetry equipment"); and

   f. The difference between the measurement made in subdivision e of subsection 1 of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

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

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

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

a. Electrical interlocks at each teletherapy room entrance;

b. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

c. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

d. Viewing and intercom systems;

e. Treatment room doors from inside and outside the treatment room; and

f. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

5. If the results of the checks required in subsection 4 of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

6. A licensee shall retain a record of each spot-check required by subsections 1 and 4 of this section, and a copy of the procedures required by subsection 2, in accordance with section 33-10-07.1-113 ("records of periodic spot-checks for teletherapy units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-69. Periodic spot-checks for remote afterloader units.

1. A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

a. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

b. Before each patient treatment with a low dose-rate remote afterloader unit; and

c. After each source installation.

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

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

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

a. Electrical interlocks at each remote afterloader unit room entrance;

b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

c. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

d. Emergency response equipment;

e. Radiation monitors used to indicate the source position;

f. Timer accuracy;
g. Clock (date and time) in the unit's computer; and
h. Decayed source activity in the unit's computer.

5. If the results of the checks required in subsection 4 of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

6. A licensee shall retain a record of each check required

by subsection 4 and a copy of the procedures required by subsection 2 of this section in accordance with section 33-10-07.1-114 ("records of periodic spot-checks for remote afterloader units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-70. Periodic spot-checks for gamma stereotactic radiosurgery units.

1. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

   a. Monthly;

   b. Before the first use of the unit on a given day; and

   c. After each source installation.

2. A licensee shall:

   a. Perform the measurements required by subsection 1 of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

   b. Have the authorized medical physicist review the results of each spot-check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

3. To satisfy the requirements of subdivision a of subsection 1 of this section, spot-checks must, at a minimum:

   a. Assure proper operation of:

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

(2) Helmet microswitches;

(3) Emergency timing circuits; and

(4) Stereotactic frames and localizing devices (trunnions).

b. Determine:

(1) The output for one typical set of operating conditions measured with the dosimetry system described in subsection 2 of section 33-10-07.1-64 ("dosimetry equipment");

(2) The difference between the measurement made in paragraph 1 of subdivision b of subsection 3 of this section 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);

(3) Source output against computer calculation;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) Trunnion centricity.

4. To satisfy the requirements of subdivisions b and c of subsection 1 of this section, spot-checks must assure proper operation of:

a. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

b. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

c. Viewing and intercom systems;

d. Timer termination;

e. Radiation monitors used to indicate room exposures; and

f. Emergency off buttons.

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

6. If the results of the checks required in subsection 4 of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7. A licensee shall retain a record of each check required by subsections 3 and 4 and a copy of the procedures required by subsection 2 of this section in accordance with section 33-10-07.1-115 ("records of periodic spot-checks for gamma stereotactic radiosurgery units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-71. Additional technical requirements for mobile remote afterloader units.

1. A licensee providing mobile remote afterloader service shall:

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

   b. Account for all sources before departure from a client's address of use.

2. In addition to the periodic spot-checks required by section 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

   a. Electrical interlocks on treatment area access points;

   b. Source exposure indicator lights on the remote

afterloader unit, on the control console, and in the facility;

c. Viewing and intercom systems;

d. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

e. Radiation monitors used to indicate room exposures;

f. Source positioning (accuracy); and

g. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

3. In addition to the requirements for checks in subsection 2, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

4. If the results of the checks required in subsection 2 of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

5. A licensee shall retain a record of each check required by subsection 2 of this section in accordance with section 33-10-07.1-116 ("records of additional technical requirements for mobile remote afterloader units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-72. Radiation surveys.

1. In addition to the survey requirement in subsection 1 of section 33-10-04.1-09 ("survey and monitoring"), a person licensed under sections 33-10-07.1-59 through 33-10-07.1-75 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

2. The licensee shall make the survey required by subsection

1 of this section at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of the unit or a source.

3. A licensee shall retain a record of the radiation surveys required by subsection 1 of this section in accordance with section 33-10-07.1-117 ("records of surveys of therapeutic treatment units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-73. Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

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

2. This inspection and servicing may only be performed by persons specifically licensed to do so by the United States nuclear regulatory commission or an agreement state or a licensing state.

3. A licensee shall keep a record of the inspection and servicing in accordance with section 33-10-07.1-118 ("records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-74. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays;

4. The accuracy of the software used to determine sealed source positions from radiographic images; and

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

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-75. Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an authorized user of a sealed source for a use authorized under section 33-10-07.1-59 ("use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit") to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 of this section and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

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

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

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

(d) Radiation biology; and

(2) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this section (33-10-07.1-75) or equivalent requirements of the United States nuclear regulatory commission, an agreement state or a licensing state at a medical institution, involving:

(a) Reviewing full calibration measurements and periodic spot-checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a medical event involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered; and

b. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this section (33-10-07.1-75) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, as part of a formal training program approved by the residency review committee for radiation oncology of the accreditation council for graduate medical education or the committee on postdoctoral training of the american osteopathic association. This experience may be obtained concurrently with the supervised work experience required by paragraph 2 of subdivision a of subsection 2 of this section; and

c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 2 of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in this section (33-10-07.1-75) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-76. Radiation safety officer. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in section 33-10-07.1-14 ("authority and responsibilities for the radiation protection program") to be an individual who:

1. Is certified by the:

   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:

(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 identified as the radiation safety officer on a United States nuclear regulatory commission or agreement state or licensing state license that authorizes the medical use of radioactive material; or

3. Is an authorized user identified on the licensee's license.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-77. Training for uptake, dilution, and excretion studies. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of a radiopharmaceutical in subsection 1 of section 33-10-07.1-35 ("use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required") to be a physician who:

1. Is certified in:

   a. Nuclear medicine by the american board of nuclear medicine;

   b. Diagnostic radiology by the american board of radiology;

   c. Diagnostic radiology or radiology by the american osteopathic board of radiology;

   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:

      (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 supervised clinical experience under the supervision of an authorized user and that includes:

      (1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

      (2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(3) Administering dosages to patients or human research subjects and 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 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 the topics identified in subsection 2 of this section.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-78. Training for imaging and localization studies. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in subsection 1 of section 33-10-07.1-37 ("use of unsealed radioactive material for imaging and localization studies for which a written directive is not required") to be a physician who:

1. Is certified in:

   a. Nuclear medicine by the american board of nuclear medicine;

   b. Diagnostic radiology by the american board of radiology;

   c. Diagnostic radiology or radiology by the american osteopathic board of radiology;

   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, generators, and reagent kits, 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) Radiopharmaceutical chemistry; and

(5) Radiation biology; and

b. Five hundred hours of supervised work experience under the supervision of an authorized user that includes:

(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 a medical event involving 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 supervised clinical experience under the supervision of an authorized user that includes:

(1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(3) Administering dosages to patients or human research subjects and 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 subsection 2 of this section.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-79. Training for therapeutic use of unsealed radioactive material. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of radiopharmaceuticals in section 33-10-07.1-41 ("use of unsealed radioactive material for which a written directive is required") to be a physician who:

1. Is certified by:

a. The american board of nuclear medicine;

b. The american board of radiology in radiology, therapeutic radiology, or radiation oncology;

c. The royal college of physicians and surgeons of Canada in nuclear medicine; or

d. The american osteopathic board of radiology after 1984; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

a. Eighty 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; 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 in ten individuals; and

(2) Use of iodine-131 for treatment of thyroid carcinoma in three individuals.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-80. Training for treatment of hyperthyroidism. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee

shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

1. Eighty hours of classroom and laboratory training that includes:

   a. Radiation physics and instrumentation;

   b. Radiation protection,

   c. Mathematics pertaining to the use and measurement of radioactivity; and

   d. Radiation biology; and

2. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-81. Training for treatment of thyroid carcinoma. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

1. Eighty hours of classroom and laboratory training that includes:

   a. Radiation physics and instrumentation;

   b. Radiation protection;

   c. Mathematics pertaining to the use and measurement

of radioactivity; and

d. Radiation biology; and

2. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three individuals.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-82. Training for use of brachytherapy sources. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of a brachytherapy source listed in section 33-10-07.1-47 ("use of sources for manual brachytherapy") for therapy to be a physician who:

1. Is 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; and

(4) Radiation biology;

b. Five hundred hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(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 a medical event involving 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.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-83. Training for ophthalmic use of strontium-90. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall 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:

1. Twenty four hours of classroom and laboratory training that includes:

   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 individual's case history.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-84. Training for use of sealed sources for diagnosis. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of a sealed source in a device listed in section 33-10-07.1-57 ("use of sealed sources for diagnosis") to be a physician, dentist, or podiatrist who:

1. Is certified in:

   a. Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the american board of radiology;

   b. Nuclear medicine by the american board of nuclear medicine;

   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:

   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.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-85. Training for use of therapeutic medical devices. Except as provided in section 33-10-07.1-23 ("training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist"), the licensee shall require the authorized user of a sealed source listed in section 33-10-07.1-59 ("use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit") to be a physician who:

1. Is 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, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, 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; and

      (4) Radiation biology;

   b. Five hundred hours of supervised 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 medical events;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

(5) Checking and using survey meters; 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 teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

(2) Selecting the proper dose and how it is to be administered;

(3) Calculating the 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 patients' or human research subjects' reaction to radiation; and

(4) Post-administration follow up and review of case histories.

History:
General Authority: NDCC 23-20.1-04

Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-86. Training for an authorized medical physicist. The licensee shall require the authorized medical physicist to be an individual who:

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 of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in sections 33-10-07.1-29 ("requirements for possession of sealed sources and brachytherapy sources"), 33-10-07.1-53 ("decay of strontium-90 sources for ophthalmic treatments"), 33-10-07.1-65 ("full calibration measurements on teletherapy units"), 33-10-07.1-66 ("full calibration measurements on remote afterloader units"), 33-10-07.1-67 ("full calibration measurements on gamma stereotactic radiosurgery units"), 33-10-07.1-68 ("periodic spot-checks for teletherapy units"), 33-10-07.1-69 ("periodic spot-checks for remote afterloader units"), 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units"), and 33-10-07.1-72 ("radiation surveys"), as applicable.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-87. Training for an authorized nuclear pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

1. Has current board certification as a nuclear pharmacist by the board of pharmaceutical specialties; or

2. a. Has completed seven hundred hours in a structured educational program consisting of both:

(1) Didactic training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Supervised experience in a nuclear pharmacy involving the following:

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

(b) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

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

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

b. 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.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-88. 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 subdivision a of subsection 2 of section 33-10-07.1-87 ("training for an authorized nuclear pharmacist") before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (subdivision b of subsection 2 of section 33-10-07.1-87) and recentness of training (section 33-10-07.1-24) to qualify as an authorized nuclear pharmacist.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-89. Other medical uses of radioactive material or radiation from radioactive material. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in sections 33-10-07.1-35 through 33-10-07.1-75 if:

1. The applicant or licensee has submitted the information required by subsections 2 through 4 of section 33-10-07.1-08 ("application for license, amendment, or renewal"); and

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

History:

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-90. Records of authority and responsibilities for radiation protection programs.

1. A licensee shall retain a record of actions taken by the licensee's management in accordance with subsection 1 of section 33-10-07.1-14 ("authority and responsibilities for the radiation protection program") for five years. The record must include a summary of the actions taken and a signature of licensee management.

2. The licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer as required by subsection 5 of section 33-10-07.1-14 ("authority and responsibilities for the radiation protection program"), and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by subsection 2 of section 33-10-07.1-14 ("authority and responsibilities for the radiation protection program"), for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-91. Records of radiation protection program changes. A licensee shall retain a record of each radiation protection program change made in accordance with subsection 1 of section 33-10-07.1-15 ("radiation protection program changes") for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-92. Records of written directives. A licensee shall retain a copy of each written directive as required by

section 33-10-07.1-17 ("written directives") for three years.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-93. Records for procedures for administrations requiring a written directive. A licensee shall retain a copy of the procedures required by subsection 1 of section 33-10-07.1-18 ("procedures for administrations requiring a written directive") for the duration of the license.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-94. Records of calibrations of instruments used to measure the activity of unsealed radioactive material. A licensee shall maintain a record of instrument calibrations required by section 33-10-07.1-25 ("possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material") for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-95. Records of radiation survey instrument calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by section 33-10-07.1-26 ("calibration of survey instruments") for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-96. Records of dosages of unsealed radioactive

material for medical use.

1. A licensee shall maintain a record of dosage determinations required by section 33-10-07.1-27 ("determination of dosages of unsealed radioactive material for medical use") for three years.

2. The record must contain:

   a. The radiopharmaceutical;

   b. The patient's or human research subject's name, or identification number if one has been assigned;

   c. The prescribed dosage, the determined dosage, or a notation that the total activity is less than one thousand one hundred kilobecquerels [thirty microcuries];

   d. The date and time of the dosage determination; and

   e. The name of the individual who determined the dosage.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-97. Records of leak tests and inventory of sealed sources and brachytherapy sources.

1. A licensee shall retain records of leak tests required by subsection 2 of section 33-10-07.1-29 ("requirements for possession of sealed sources and brachytherapy sources") for three years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

2. A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by subsection 7 of section 33-10-07.1-29 ("requirements for possession of sealed sources and brachytherapy sources") for three years. The inventory records must contain the model number of each source, and

serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-98. Records of surveys for ambient radiation exposure rate. A licensee shall retain a record of each survey required by section 33-10-07.1-31 ("surveys of ambient radiation exposure rate") for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-99. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"), if the total effective dose equivalent is calculated by:

   a. Using the retained activity rather than the activity administered;

   b. Using an occupancy factor less than twenty five hundredths at one meter;

   c. Using the biological or effective half-life; or

   d. Considering the shielding by tissue.

2. A licensee shall retain a record that the instructions required by subsection 2 of section 33-10-07.1-32 ("release of individuals containing unsealed radioactive

material or implants containing radioactive material") were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts [five hundred millirems].

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

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-100. Records of mobile medical services.

1. A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by subdivision a of subsection 1 of section 33-10-07.1-33 ("provision of mobile medical service"). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service.

2. A licensee shall retain the record of each survey required by subdivision d of subsection 1 of section 33-10-07.1-33 ("provision of mobile medical service") for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-101. Records of decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by section 33-10-07.1-34 ("decay-in-storage"), for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-102. Records of molybdenum-99 concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by subsection 2 of section 33-10-07.1-38 ("permissible molybdenum-99 concentrations") for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-103. Records of aluminum ion concentrations. A licensee shall maintain a record of the aluminum ion concentration tests required by section 33-10-07.1-39 ("permissible aluminum ion concentrations") for three years.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-104. Records of safety instruction. A licensee shall maintain a record of safety instructions required by sections 33-10-07.1-42 ("safety instruction for the use of unsealed radioactive material for which a written directive is required"), 33-10-07.1-50 ("safety instruction for the use of sources for manual brachytherapy"), and 33-10-07.1-62 ("safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units") for three years. The record must include a list of the topics covered, the date of the instruction, the name of each attendee, and the name of each individual who provided the instruction.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-105. Records of surveys after source implant and removal. A licensee shall maintain a record of the surveys required by sections 33-10-07.1-48 ("surveys after source implant and removal") and 33-10-07.1-60 ("surveys of patients and human research subjects treated with a remote afterloader unit") for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-106. Records of brachytherapy source accountability.

1. A licensee shall maintain a record of brachytherapy source accountability required by section 33-10-07.1-49 ("brachytherapy sources accountability") for three years.

2. For temporary implants, the record must include:

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

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

3. For permanent implants, the record must include:

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

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

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

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-107. Records of calibration measurements of brachytherapy sources.

1. A licensee shall maintain a record of the calibrations of brachytherapy sources required by section 33-10-07.1-52 ("calibration measurements of brachytherapy sources") for three years after the last use of the source.

2. The record must include:

   a. The date of the calibration;

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

   c. The source output or activity;

   d. The source positioning accuracy within the applicators; and

   e. The signature of the authorized medical physicist.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-108. Records of decay of strontium-90 sources for ophthalmic treatments.

1. A licensee shall maintain a record of the activity of a strontium-90 source required by section 33-10-07.1-53 ("decay of strontium-90 sources for ophthalmic treatments") for the life of the source.

2. The record must include:

   a. The date and initial activity of the source as determined under section 33-10-07.1-52 ("calibration measurements of brachytherapy sources"); and

b. For each decay calculation, the date and the source activity as determined under section 33-10-07.1-53 ("decay of strontium-90 sources for ophthalmic treatments").

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-109. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by section 33-10-07.1-61 ("installation, maintenance, adjustment, and repair") for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and the name of each individual who performed the work.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-110. Records of safety procedures. A licensee shall retain a copy of the procedures required by subdivision d of subsection 1 of section 33-10-07.1-62 ("safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units") and subdivision b of subsection 4 of section 33-10-07.1-62 until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-111. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with section 33-10-07.1-64

("dosimetry equipment") for the duration of the license.

2. For each calibration, intercomparison, or comparison, the record must include:

   a. The date;

   b. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 1 and 2 of section 33-10-07.1-64 ("dosimetry equipment");

   c. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

   d. The names of the individuals who performed the calibration, intercomparison, or comparison.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-112. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

1. A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by sections 33-10-07.1-65 ("full calibration measurements on teletherapy units"), 33-10-07.1-66 ("full calibration measurements on remote afterloader units"), and 33-10-07.1-67 ("full calibration measurements on gamma stereotactic radiosurgery units") for three years.

2. The record must include:

   a. The date of the calibration;

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

   c. The results and an assessment of the full

calibrations;

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

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

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-113. Records of periodic spot-checks for teletherapy units.

1. A licensee shall retain a record of each periodic spot-check for teletherapy units required by section 33-10-07.1-68 ("periodic spot-checks for teletherapy units") for three years.

2. The record must include:

   a. The date of the spot-check;

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

   c. An assessment of timer linearity and constancy;

   d. The calculated on-off error;

   e. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

   f. The determined accuracy of each distance measuring and localization device;

   g. The difference between the anticipated output and the measured output;

   h. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and

doors; and

i. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

3. A licensee shall retain a copy of the procedures required by subsection 2 of section 33-10-07.1-68 ("periodic spot-checks for teletherapy units") until the licensee no longer possesses the teletherapy unit.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-114. Records of periodic spot-checks for remote afterloader units.

1. A licensee shall retain a record of each spot-check for remote afterloader units required by section 33-10-07.1-69 ("periodic spot-checks for remote afterloader units") for three years.

2. The record must include, as applicable:

   a. The date of the spot-check;

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

   c. An assessment of timer accuracy;

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

   e. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

3. A licensee shall retain a copy of the procedures required by subsection 2 of section 33-10-07.1-69 ("periodic spot-checks for remote afterloader units") until the licensee

no longer possesses the remote afterloader unit.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-115. Records of periodic spot-checks for gamma stereotactic radiosurgery units.

1. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by section 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units") for three years.

2. The record must include:

   a. The date of the spot-check;

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

   c. An assessment of timer linearity and accuracy;

   d. The calculated on-off error;

   e. A determination of trunnion centricity;

   f. The difference between the anticipated output and the measured output;

   g. An assessment of source output against computer calculations;

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

   i. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the

record of the spot-check.

3. A licensee shall retain a copy of the procedures required by subsection 2 of section 33-10-07.1-70 ("periodic spot-checks for gamma stereotactic radiosurgery units") until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-116. Records of additional technical requirements for mobile remote afterloader units.

1. A licensee shall retain a record of each check for mobile remote afterloader units required by section 33-10-07.1-71 ("additional technical requirements for mobile remote afterloader units") for three years.

2. The record must include:

   a. The date of the check;

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

   c. Notations accounting for all sources before the licensee departs from a facility;

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

   e. The signature of the individual who performed the check.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-117. Records of surveys of therapeutic treatment

units.

1. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with section 33-10-07.1-72 ("radiation surveys") for the duration of use of the unit.

2. The record must include:

   a. The date of the measurements;

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

   c. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

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

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-118. Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

1. A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by section 33-10-07.1-73 ("five-year inspection for teletherapy and gamma stereotactic radiosurgery units") for the duration of use of the unit.

2. The record must contain:

   a. The inspector's radioactive materials license number;

   b. The date of inspection;

   c. The manufacturer's name and model number and serial number of both the treatment unit and source;

   d. A list of components inspected and serviced, and

the type of service; and

e. The signature of the inspector.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-119. Report and notification of a medical event.

1. A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

   a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than fifty millisieverts [five rems] effective dose equivalent, five hundred millisieverts [fifty rems] to an organ or tissue, or five hundred millisieverts [fifty rems] shallow dose equivalent to the skin; and

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

      (2) The total dosage delivered differs from the prescribed dosage by twenty percent or more or falls outside the prescribed dosage range; or

      (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty percent or more.

   b. A dose that exceeds fifty millisieverts [five rems] effective dose equivalent, five hundred millisieverts [fifty rems] to an organ or tissue, or five hundred millisieverts [fifty rems] shallow dose equivalent to the skin from any of the following:

      (1) An administration of a wrong radioactive drug containing radioactive material;

      (2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

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

(4) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(5) A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by five hundred millisieverts [fifty rems] to an organ or tissue and fifty percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

2. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

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

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

a. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on each individual who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

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

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

5. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty four hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

7. A licensee shall:

a. Annotate a copy of the report provided to the department with the:

(1) Name of the individual who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-120. Report and notification of a dose to an embryo, a fetus, or a nursing child.

1. A licensee shall report any dose to an embryo or a fetus that is greater than fifty millisieverts [five rems] dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by the authorized user.

2. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

   a. Is greater than fifty millisieverts [five rems] total effective dose equivalent; or

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

3. The licensee shall notify the department by telephone no later than the next calendar day after discovery of a dose to the embryo or fetus or nursing child that requires a report in subsections 1 or 2 in this section.

4. The licensee shall submit a written report to the department within fifteen days after discovery of a dose to the embryo or fetus or nursing child that requires a report in subsections 1 or 2 of this section.

   a. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

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

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

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

5. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty four hours after discovery of an event that would require reporting under subsection 1 or 2 of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty four hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo or fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall

provide such a written description if requested.

6. A licensee shall:

a. Annotate a copy of the report provided to the department with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-121. Report of a leaking source. A licensee shall file a report within five days if a leak test required by section 33-10-07.1-29 ("requirements for possession of sealed sources and brachytherapy sources") reveals the presence of one hundred eighty five becquerels [five thousandths microcurie] or more of removable contamination. The report must be filed with the department. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04