CHAPTER 33-10-05
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL 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.

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. "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 specified in subsection 1 of section 33-10-04.1-07.

2. "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. "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.

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

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

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

7. "Permanent radiographic installation" means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.

8. "Personal supervision" means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is physically present at the site, in visual contact with the trainee while the trainee is using sources of radiation and associated equipment, and in such proximity that immediate assistance can be given if required.

9. "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.

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. "Radiographic exposure device" 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.

13. "Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee.

14. "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.

15. "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.

16. "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.

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

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

21. "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.

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 radiography equipment.** Equipment used in industrial radiographic operations must meet the following minimum criteria:

   a. Each radiographic exposure device 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.

(1) Each radiographic exposure device must have 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 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 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 and associated equipment that allow the source to be moved out of the device for routine operation.

(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 crushing tests for the control tube as specified in American national standards institute N432-1980 and a kinking resistance test that closely approximates the 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.**

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.**

a. Each source of radiation 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 at all times except when under the direct surveillance of a radiographer or radiographer trainee, 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.

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.

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.

(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.

c. Records of these calibrations must be maintained for two 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 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 this article. 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".

7. **Quarterly inventory.** Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and radiography exposure devices received or possessed by the licensee. The records of the inventories shall be maintained for two 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 years from the date of the recorded event, showing for each source of radiation the following information:

   a. A unique identification, such as serial number, of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source.

   b. The identity 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.

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 repairs have been made.

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 both 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.

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.

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

33-10-05-04.1. Exemptions. Repealed effective March 1, 1994.

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

1. **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:

(1) The subjects outlined in appendix A of this chapter;

(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;

(3) The appropriate department license or certificate of registration; and

(4) 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;

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

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

(3) 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;

(4) Has demonstrated an understanding of the instructions in subdivision a of subsection 1 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, an examination administered by the department or a third party designated by the department.

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

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.

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.

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

a. 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. Methods and occasions for conducting radiation surveys.

c. Methods for controlling access to radiographic areas.

d. Methods and occasions for locking and securing sources of radiation.

e. 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. Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation.

g. Minimizing exposure of individuals in the event of an accident.

h. The procedure for notifying proper personnel in the event of an accident.

i. Maintenance of records.

j. The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines.

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 may 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.

4. **Supervision of radiographer trainee.** Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools, 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 trainee shall be under the personal supervision of a radiographer instructor.

5. **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 trainee training requirements in subdivision a of subsection 1.

(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.

(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.

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.

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:

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.

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 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 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.

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) for each individual;

(3) An operable, calibrated pocket dosimeter with a range of zero to five hundred sixteen ten millionths coulombs per kilogram [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 [500 milliroentgens] per hour; and

(5) The appropriate barrier ropes and signs.

b. Industrial radiographic operations may not be performed if any of the items specified in subdivision a of 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. 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 trainee who is under the personal supervision of a radiographer instructor 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. During an inspection by the department, the department inspector may terminate an operation if any of the items required in subdivision a of subsection 5 are not available and 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 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 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 paragraph 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 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 TRAINEES

Training provided to qualify individuals as radiographer trainees in compliance with subdivision a of subsection 1 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 sievert) and quantity of radioactivity (curie or 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
    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

(2) Thermoluminescent dosimeters (TLD's)

(3) Pocket dosimeters

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

d. Operation and control of X-ray equipment

e. Collimators

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

CHAPTER 33-10-06
X-RAYS IN THE HEALING ARTS

33-10-06-01. Scope. This chapter establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The requirements of this chapter are in addition to, and not in substitution for, 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

33-10-06-02. Definitions. As used in this chapter, the following definitions apply:

1. "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
2. "Added filtration" means any filtration which is in addition to the inherent filtration.
3. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is

ninety-nine percent minimum aluminum, twelve-hundredths percent copper.)

4. "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

5. "Attenuation block" means a block or stack, having dimensions twenty centimeters by twenty centimeters by three and eight-tenths centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

6. "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location or locations a required quantity of radiation (includes devices such as phototimers and ion chambers).

7. "Barrier" (see "protective barrier").

8. "Beam axis" means a line from the source through the centers of the X-ray fields.

9. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the X-ray field.

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

11. "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

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

13. "Certified components" means components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 [Pub. L. 90-602].

14. "Certified system" means any X-ray system which has one or more certified component or components.

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

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

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left| \sum_{i=1}^{n} \frac{(X_i - \bar{X})^2}{n-1} \right|^{1/2}$$

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

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

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

19. "Control panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

20. "Cooling curve" means the graphical relationship between heat units stored and cooling time.

21. "CT" (see "computed tomography").

22. "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

23. "Detector" (see "radiation detector").

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

25. "Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission, and reception of X-rays and the transformation, storage, and visual display of the resultant X-ray image.

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

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

28. "Entrance radiation exposure rate" means the radiation exposure free in air per unit time at the point where the center of the useful beam enters the patient.

29. "Equipment" (see "X-ray equipment").

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

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

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

33. "Focal spot (actual)" means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

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

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

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

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

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

39. "HVL" (see "half-value layer").

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

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

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

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

44. "Irradiation" means the exposure of matter to ionizing radiation.

45. "Kilovolts peak" (see "peak tube potential").

46. "kV" means kilovolts.

47. "kVp" (see "peak tube potential").

48. "kWs" means kilowatt second. It is equivalent to 10^3 kV·mA·s, i.e.,

$$(A)\text{kWs} = (X)\text{kV} \times (Y)\text{mA} \times (Z)\text{s} \times \frac{\text{kWs}}{10^3\text{kV} \times \text{mA} \times \text{s}} = \frac{XYZ\ \text{kWs}}{10^3}$$

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

50. "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

    a. The useful beam.

    b. Radiation produced when the exposure switch or timer is not activated.

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

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

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

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

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

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

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

Percent line-voltage regulation = $100\ (V_n - V_l)\ /V_l$

where:
V_n = No-load line potential and
V_l = Load line potential

55. "mA" (see milliampere).

56. "mAs" (see milliampere second).

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

58. "Milliampere" as used in this chapter applies to X-ray tube current.

59. "Milliampere second" as used in this chapter is the product of the tube current and X-ray exposure time measured in seconds.

60. "Mobile X-ray equipment" (See "X-ray equipment").

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

62. "PBL" has the same meaning as "positive beam limitation".

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

64. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

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

66. "PID" has the same meaning as "position indicating device".

67. "Portable X-ray equipment" (see "X-ray equipment").

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

69. "Positive beam limitation" means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

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

71. "Primary protective barrier" (see "protective barrier").

72. "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

73. "Protective barrier" means a barrier of radiation absorbing material or materials used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam;

b. "Secondary protective barrier" means the material which attenuates stray radiation.

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

75. "Qualified expert" means an individual having the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American board of radiology, or the American board of health physics, or the American board of medical physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, "qualified expert" means an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in therapeutic radiological physics or X-ray and radium physics by the American board of radiology, or those having equivalent qualifications.

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

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

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

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

80. "Radiological physicist" means an individual who:

a. Is certified by the American board of radiology in therapeutic radiological physics, radiological physics, or X-ray and gamma-ray physics; or

b. Has a bachelor's degree in one of the physical sciences or engineering and three year's full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American board of radiology. The work duties must include duties involving the

calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

c. Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

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

82. "Recording" means producing a permanent form of an image resulting from X-ray photons.

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

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

85. "Secondary protective barrier" (see "protective barrier").

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

87. "SID" has the same meaning as "source-image receptor distance".

88. "Source" means the focal spot (actual) of the X-ray tube.

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

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

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

92. "Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device

intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

93. "SSD" means the distance between the source and the skin entrance plane of the patient.

94. "Stationary X-ray equipment" (see "X-ray equipment").

95. "Stray radiation" means the sum of leakage and scattered radiation.

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

    a. For capacitor energy storage equipment, peak tube potential in kilovolts and quantity of charge in milliampere second.

    b. For field emission equipment rated for pulsed operation, peak tube potential in kilovolts and number of X-ray pulses.

    c. For CT X-ray systems designed for pulsed operation, peak tube potential in kilovolts, scan time in seconds, and either tube current in milliampere, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in milliampere second.

    d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kilovolts, and either tube current in milliampere and scan time in seconds, or the product of tube current and exposure time in milliampere second and the scan time when the scan time and exposure time are equivalent.

    e. For all other equipment, peak tube potential in kilovolt and either tube current in milliampere and exposure time in seconds, or the product of tube current and exposure time in milliampere second.

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

98. "Tomogram" means the depiction of X-ray attenuation properties of a section through the body.

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

100. "Tube" means an X-ray tube, unless otherwise specified.

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

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

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

104. "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given source-image receptor distance.

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

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

107. "X-ray exposure control" means a device, switch, button, or other similar means by which the operator initiates or terminates, or both, the radiation exposure. It may include equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices.

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

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

b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.

c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.

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

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

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

112. "X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

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

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-03. General requirements.

1. **Administrative controls.**

   a. Registrant. The registrant shall be responsible for directing the operation of the X-ray systems which have been registered with the department. The registrant or the registrant's agent shall assure that the requirements are met in the operation of the X-ray system.

      (1) An X-ray system which does not meet the requirements of this article shall not be operated for diagnostic or therapeutic purposes.

      (2) Individuals who will be operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment commensurate with the size, scope, and nature of the service. As a minimum, individuals shall be instructed in and demonstrate competence in subjects outlined in appendix F of this chapter. The department may use interview, observation or testing, or both, to determine compliance. Records must be maintained by the registrant to demonstrate compliance with this paragraph.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel, which specifies for all examinations performed with that system the following information:

(a) Patient's body part and anatomical size or body thickness, or age (for pediatrics), versus technique factors to be utilized.

(b) Type and size of the film or film-screen combination to be used.

(c) Type and focal distance of the grid to be used, if any.

(d) Source-image receptor distance to be used (except for dental intraoral radiography).

(e) Type and location of placement of gonad shielding to be used.

(f) For mammography, indication of kVp/target/filter combination.

(4) The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding restrictions and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

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

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than five-tenths millimeter lead equivalent material.

(b) The X-ray operator, other staff, ancillary personnel, and other persons required for the X-ray procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than twenty-five one-hundredths millimeter lead equivalent material.

(c) Human patients who cannot be removed from the room shall be protected from the direct scatter

radiation by whole body protective barriers of not less than twenty-five one-hundredths millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than five-tenths millimeter lead equivalent material must be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

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

(a) Exposure of an individual for training, demonstration or other non-healing-arts purposes.

(b) Exposure of an individual for the purpose of healing arts screening except as authorized by paragraph 11.

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The safety rules, required by this section shall list individual projections where holding devices cannot be utilized.

(b) Written safety procedures, as required by paragraph 4, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(c) The human holder shall be instructed in personal radiation safety and protected as required by paragraph 5.

(d) No individual shall be used routinely to hold film or patients.

(e) In those cases where the patient must hold the film, except during intraoral examinations, any

portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five-tenths millimeter lead equivalent material.

(f) A record shall be made of the examination and shall include the name of the human holder, date of the examination, number of exposures, and technique factors utilized for the exposure.

(g) Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:

(a) The speed of film and screen combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography, therapeutic portal imaging, and standard film packets for intraoral use in dental radiography.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) Proper film handling and processing procedures. Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with appendix D.

(d) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patients to a stationary X-ray installation.

(e) X-ray systems subject to section 33-10-06-06 shall not be utilized in procedures where the source to patient distance is less than thirty centimeters, except for veterinary systems.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of section 33-10-04.1-06, "Occupational dose limits". In addition:

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

[1] When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

[2] The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by subsection 7 of section 33-10-04.1-15. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

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

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the department. When requesting such approval, that person shall submit the information outlined in appendix E of this chapter. If any information submitted to the department becomes invalid or outdated, the department shall be immediately notified.

b. Information and maintenance record and associated information. The registrant shall maintain the following information for each X-ray system for inspection by the department:

(1) Maximum rating of technique factors.

(2) Model and serial numbers of all certifiable components and user's manuals for those components.

(3) Aluminum equivalent filtration of the useful beam, including any routine variation.

(4) Tube rating charts and cooling curves.

(5) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system with the names of persons who performed such services.

(6) A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

(a) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

(b) The type and thickness of materials, or lead equivalency, of each protective barrier.

(7) A copy of all correspondence with this department regarding that X-ray system.

c. X-ray log.

(1) Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, and the dates those examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(2) Veterinary facilities shall maintain an X-ray utilization log indicating the type of examinations, the date of the examinations and if the patient or film was provided with human auxiliary support, the name of the human holder.

2. **Plan review.**

a. Prior to construction, the floor plans, shielding specifications, and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be submitted to the department for review and approval. The required information is denoted in appendices A, B, and C of this chapter.

b. The department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

c. The approval of such plans shall not preclude the requirement of additional modifications should a

subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in sections 33-10-04.1-06 and 33-10-04.1-07.

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

33-10-06-04. General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

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

2. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed one hundred milliroentgens in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

4. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

5. Beam quality.

   a. Half-value layer.

      (1) The half-value layer (HVL) of the useful beam for a given X-ray tube potential shall not be less than the values shown in table I. If it is necessary to determine such half-value layer at an X-ray tube

potential which is not listed in table I, linear interpolation or extrapolation may be made.

TABLE 1

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts Peak)	Half-Value Layer In Millimeters Aluminum	
		Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(2) For capacitor energy storage equipment, compliance with the requirements of this subsection shall be determined with the system fully charged and a setting of ten mAs for each exposure.

(3) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are permanently present between the source and the patient.

(4) For mammography systems with molybdenum filter and molybdenum target, measured half-value layer (HVL) with compression device in the X-ray beam shall be greater than or equal to the kilovolts peak (kVp) divided by one hundred, millimeters aluminum and less

than or equal to the kilovolts peak (kVp) divided by one hundred plus one-tenth millimeter aluminum.

$$HVL \geq (kVp/100)\ mmAl \text{ and } \leq (kVp/100) + 0.1\ mmAl$$

b. Filtration controls. For X-ray systems which have variable kilovolts peak and variable filtration for the useful beam, a device shall link the kilovolts peak selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by paragraph 1 of subdivision a is in the useful beam for the given kilovolts peak which has been selected.

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

7. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

8. Technique indicators.

   a. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

   b. The requirements of subdivision a may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operators position except in the case of spot films made by the fluoroscopist.

9. Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the federal X-ray equipment performance standard (21 CFR part 1020) shall be maintained in compliance with applicable requirements of that standard.

10. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.

11. Structural shielding requirements (see appendix C).

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

33-10-06-05. Fluoroscopic X-ray systems. All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

1. **Limitation of useful beam.**

   a. Primary barrier.

      (1) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-image receptor distance (SID).

      (2) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

   b. X-ray field.

      (1) For certified fluoroscopic systems with or without a spot-film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the source-image receptor distance. The sum of the excess length and the excess width shall be no greater than four percent of the source-image receptor distance.

      (2) For uncertified fluoroscopic systems with a spot-film device, the X-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot-film size for which the device is designed. Measurements shall be made at the minimum source image distance available but at no less than twenty centimeters tabletop to the film plane distance.

      (3) For uncertified fluoroscopic systems without a spot-film device, the requirements of paragraph 1 apply.

      (4) Other requirements for fluoroscopic beam limitation:

         (a) Means shall be provided to permit further limitation of the field. Beam-limiting devices

manufactured after May 22, 1979, and incorporated in equipment with a variable source-image receptor distance and/or a visible area of greater than three hundred square centimeters shall be provided with means for stepless adjustment of the X-ray field.

(b) All equipment with a fixed source-image receptor distance and a visible area of three hundred square centimeters or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to one hundred twenty-five square centimeters or less. Stepless adjustment shall, at the greatest source-image receptor distance, provide continuous field sizes from the maximum obtainable to a field size of five by five centimeters or less.

(c) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

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

(5) Spot-film devices shall meet the following additional requirements:

(a) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(b) Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the source-image receptor distance when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent of the source-image receptor distance.

(c) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest source-image receptor distance shall be equal to, or less than, five centimeters by five centimeters.

(d) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the source-image receptor distance.

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

(6) If a means exists to override any of the automatic X-ray field size adjustments required in subdivision b of subsection 1 that means:

(a) Must be designed for use only in the event of system failure.

(b) Must incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden.

(c) Must be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

2. **Activation of the fluoroscopic tube.** X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the

entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure or exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. **Radiation exposure rate limits.**

a. Entrance radiation exposure rate allowable limits.

(1) Fluoroscopic equipment which is provided with automatic radiation exposure rate control:

(a) The radiation exposure measured at the point where the center of the useful beam enters the patient shall not exceed two and fifty-eight hundredths millicoulomb per kilogram [10 roentgens] per minute, except during recording of fluoroscopic images or when provided with optional high level control.

(b) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in a radiation exposure rate in excess of one and twenty-nine hundredths millicoulomb per kilogram [5 roentgens] per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

[1] When the high level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of five and sixteen hundredths millicoulomb per kilogram [20 roentgens] per minute at the point where the center of the useful beam enters the patient.

[2] Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.

[3] A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) Fluoroscopic equipment which is not provided with automatic radiation exposure rate control:

(a) The radiation exposure measured at the point where the center of the useful beam enters the patient shall not exceed one and twenty-nine hundredths millicoulomb per kilogram [5 roentgens] per minute, except during recording of fluoroscopic images or when provided with an optional high level control and the high level control is activated.

[1] When the high level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of five and sixteen hundredths millicoulomb per kilogram [20 roentgens] per minute at the point where the center of the useful beam enters the patient.

[2] Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.

[3] A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) Compliance with the requirements of subsection 3 of this section shall be determined as follows:

(a) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(b) If the source is below the table, the radiation exposure rate shall be measured one centimeter above the tabletop or cradle.

(c) If the source is above the table, the radiation exposure rate shall be measured at thirty centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(d) In a C-arm type of fluoroscope, both stationary and mobile units shall meet the entrance exposure rate limits specified in paragraphs 1, 2, and 3 of subdivision a of subsection 3, shall be measured thirty centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available source-image receptor distance provided that the

end of the spacer assembly or beam-limiting device is not closer than thirty centimeters from the input surface of the fluoroscopic imaging assembly.

(e) In a lateral type of fluoroscope, the exposure rate shall be measured at a point fifteen centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the X-ray table.

(4) Periodic measurement of entrance radiation exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:

(a) Such measurements shall be made annually or after any maintenance of the system which might affect the radiation exposure rate.

(b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in paragraph 5 of subdivision b of subsection 1 of section 33-10-06-03. Results of the measurements shall include the roentgen per minute, as well as the technique factors used to determine such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

(c) Conditions of periodic measurements of typical entrance radiation exposure rate are as follows:

[1] The measurement shall be made under the conditions that satisfy the requirements of paragraph 4.

[2] The kilovolts peak, mA, and other selectable parameters shall be the settings typical of clinical use on a 23 cm thick abdominal patient.

[3] The X-ray systems that incorporates automatic radiation exposure control shall have sufficient material placed in the

useful beam to produce a milliamperage or kilovoltage, or both, to satisfy the conditions of item 2 of subparagraph c of this paragraph.

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

(d) Conditions of periodic measurements of maximum entrance radiation exposure rate are as follows:

[1] The measurement shall be made under the conditions that satisfy the requirements of paragraph 3.

[2] The kVp, mA, and other selectable parameters shall be the maximum selectable parameters of clinical use of the X-ray system.

[3] The X-ray systems that incorporate automatic radiation exposure control shall have sufficient material placed in the useful beam to produce a kVp, mA, and other selectable parameters to satisfy the conditions of item 2 of subparagraph d of this paragraph.

[4] X-ray systems that do not incorporate an automatic radiation exposure control shall utilize the maximum kVp, mA, and other selectable parameters of clinical use of the X-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

4. Barrier transmitted radiation rate limits.

a. The radiation exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall not exceed five hundred sixteen thousandths microcoulomb per kilogram [2 milliroentgens] per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance radiation exposure rate.

b. Measuring compliance of barrier transmission.

(1) The radiation exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

(2) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty centimeters above the tabletop.

(3) If the source is above the tabletop and the source-image receptor distance is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than thirty centimeters.

(4) Movable grids and compression devices shall be removed from the useful beam during the measurement.

5. **Indication of potential and current.** During fluoroscopy and cinefluorography, the kilovolt and the milliampere shall be continuously indicated.

6. **Source-skin distance.** The source to skin distance shall not be less than:

a. Thirty-eight centimeters on stationary fluoroscopes installed after August 1, 1974.

b. Thirty-five and one-half centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974.

c. Thirty centimeters on all mobile fluoroscopes.

d. Twenty centimeters for all mobile fluoroscopes used for specific surgical application.

7. **Fluoroscopic timer.**

a. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal

shall continue to sound while X-rays are produced until the timing device is reset.

8. **Control of scattered radiation.**

   a. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than twenty-five one-hundredths millimeter lead equivalent.

   b. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

      (1) Is at least one hundred twenty centimeters from the center of the useful beam; or

      (2) The radiation has passed through not less than twenty-five one-hundredths millimeter lead equivalent material, including, but not limited to, drapes, bucky-slot cover-sliding or folding panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in paragraph 5 of subdivision a of subsection 1 of section 33-10-06-03.

   c. The department may grant exceptions to subdivision b of this subsection in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.

9. **Spot-film exposure reproducibility.** Fluoroscopic systems equipped with spot-film mode shall meet the exposure reproducibility requirements of subsection 5 of section 33-10-06-06 when operating in the spot-film mode.

10. **Radiation therapy simulation system.** Radiation therapy simulation systems shall be exempt from all the requirements of subsections 1, 3, 4, and 7 of section 33-10-06-05 provided that:

    a. Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

b. Such systems as do not meet the requirements of subsection 7 of section 33-10-06-05 are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

11. **Structural shielding requirements** (see appendix E).

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

33-10-06-06. Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems.

1. **Beam limitation requirements for systems without positive beam limitation including portable X-ray systems.** The useful beam shall be limited to the area of clinical interest.

   a. General purpose stationary and mobile X-ray systems including veterinary systems (other than portable) installed after January 1, 1998.

      (1) There shall be provided a means for independent length and width stepless adjustment to the size of the X-ray field.

      (2) Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

      (3) The department may grant an exemption to paragraphs 1 and 2 of this subdivision on noncertified X-ray systems, provided the registrant makes a written application for such exemption and demonstrates in the application:

         (a) That it is impractical to comply with paragraphs 1 and 2 of this subdivision; and

         (b) The purpose of paragraphs 1 and 2 of this subdivision will be met by other means.

   b. Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of

subdivision a of this subsection, all stationary X-ray systems both certified and noncertified shall meet the following requirements:

(1) Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent of the source-image receptor distance, and to indicate the source-image receptor distance to within two percent.

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.

(3) Indication of field size dimensions and source-image receptor distance's shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the source-image receptor distance when the beam axis is indicated to be perpendicular to the plane of the image receptor.

c. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at the fixed source-image receptor distance shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within two percent of the source-image receptor distance, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

d. Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated source-image receptor distance except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent of the source-image receptor distance. This requirement can be met with a system which performs as prescribed in paragraph 3 of subdivision e of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a

mammographic procedure and the source-image receptor distance may vary, the source-image receptor distance indication specified in subparagraphs a and b of paragraph 3 of subdivision e of this subsection shall be the maximum source-image receptor distance for which beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

e. X-ray systems other than those described in subdivisions a, b, c, and d and veterinary systems installed prior to January 1, 1998, and all portable veterinary X-ray systems.

(1) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the source-image receptor distance when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(2) Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the source-image receptor distance, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

(3) Paragraphs 1 and 2 of this subdivision may be met with a system that meets the requirements for a general purpose X-ray system as specified in subsection 1 of this section, or, when alignment means are also provided, may be met with either:

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

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for which the

unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and source-image receptor distance for which each aperture is designed and shall indicate which aperture is in position for use.

2. **Beam limitation requirements applicable to certified systems only.** Diagnostic X-ray systems incorporating one or more certified components shall be required to comply with the following additional requirements which relate to those certified components.

   a. Beam limitation for stationary and mobile general purpose X-ray systems.

      (1) There shall be provided a means of independent length and width stepless adjustment of the size of the X-ray field. The minimum field size at a source-image receptor distance of one hundred centimeters shall be equal to or less than five centimeters by five centimeters.

      (2) When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than one hundred sixty lux or fifteen foot-candles at one hundred centimeters or at the maximum source-image receptor distance, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

      (3) The edge of the light field at one hundred centimeters or at the maximum source-image receptor distance, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three millimeters from the edge of the light field toward the center of field; and I_2 is the illumination three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.

   b. Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of subdivision a of subsection 1 and subdivision a of subsection 2 of this section.

c. Beam limitation and alignment on stationary general purpose X-ray systems equipped with positive beam limitation (PBL). The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of this subdivision have been properly used.

(1) Positive beam limitation (PBL), when provided, shall function as described in paragraph 2 whenever all of the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder.

(b) The image receptor length and width are each less than fifty centimeters.

(c) The X-ray beam axis is within plus or minus three degrees of vertical and the source-image receptor distance is ninety centimeters to one hundred thirty centimeters inclusive; or the X-ray beam axis is within plus or minus three degrees of horizontal and the source-image receptor distance is ninety centimeters to two hundred five centimeters inclusive.

(d) The X-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus three degrees.

(e) Neither tomographic nor steroscopic radiography is being performed.

(f) The positive beam limitation system has not been intentionally overridden. The override provision is subject to paragraph 3.

(2) Positive beam limitation (PBL), when provided, shall prevent the production of X-rays when:

(a) Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by paragraph 5, from the corresponding image receptor dimensions by more than three percent of the source-image receptor distance.

(b) The sum of the length and width differences as stated in subparagraph a, without regard to sign, exceeds four percent of the source-image receptor distance.

(c) The beam-limiting device is at a source-image receptor distance for which positive beam limitation (PBL) is not designed for sizing.

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

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

[1] Must require that a key be utilized to defeat the positive beam limitation;

[2] Must require that the key remain in place during the entire time the positive beam limitation system is overridden; and

[3] Must require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION
SYSTEM FAILURE

(b) Must include a label visible to the operator that override of the positive beam limitation system is engaged.

(4) Compliance with paragraph 2 must be determined when the requirements of paragraph 1 are met. Compliance must be determined no sooner than five seconds after insertion of the image receptor.

(5) The positive beam limitation system must be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at the source-image receptor distance of one hundred centimeters must be equal to or less than five centimeters by five centimeters.

(6) The positive beam limitation system must be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in paragraph 2, then any change of image receptor size or source-image receptor distance must cause the automatic return.

3. Radiation exposure control.

a. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

b. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

c. Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(1) Manual exposure control. An X-ray control which shall be the equivalent of a dead-man switch shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:

(a) Exposure of one-half second or less; or

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

(2) Automatic exposure controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the X-ray tube potential is equal to or greater than fifty kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(c) The minimum exposure time for all equipment other than that specified in subparagraph b shall be equal to or less than one-sixtieth second or a time interval required to deliver five mAs, whichever is greater;

(d) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than six hundred mAs per exposure except that, when the X-ray tube potential is less than fifty kVp, the product of X-ray tube current and exposure time shall be limited to not more than two thousand mAs per exposure; and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph d, and manual resetting shall be required before further automatically timed exposures can be made.

d. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios [$X_1$5 a of exposure to the indicated timer setting, in units of coulombs per kilogram per second [milliroentgen per second], obtained at any two clinically used timer settings shall not differ by more than ten hundredths times their sum. This is written as:

$$(X_1 - X_2) < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1} s^{-1}$ (mR/s) values.

e. Exposure control location. The X-ray exposure control shall be so placed that the operator can view the patient while making exposure (see appendix B).

f. Operator protection, except veterinary systems.

(1) Stationary systems. Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure (see appendix B).

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

(a) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph 1 of subdivision f;

(b) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters [6.5 feet] high for operator protection during exposures, or means

shall be provided to allow the operator to be at least two and seven-tenths meters [9 feet] from the tube housing assembly during the exposure.

(3) Mammography systems shall be operable from a shielded position.

g. Operator protection for veterinary systems. All stationary, mobile, or portable X-ray systems used for veterinary work shall be provided with either a two-meter [6.5-foot] high protection barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least two and seven-tenths meters [9 feet] from the tube housing assembly during exposures.

4. **Source-to-skin distance.** All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance equal to or greater than thirty centimeters, except for veterinary systems.

5. **Radiation exposure reproducibility.** When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed five hundredths. This requirement applies to clinically used techniques. This requirement shall be deemed to have been met if, when four radiation exposures are made at identical technique factors, the value of the average radiation exposure (E) is greater than or equal to five times the maximum radiation exposure (E_{max}) minus the minimum radiation exposure (E_{min}),

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

6. **Radiation from capacitor energy storage equipment in standby status.** Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

7. **Accuracy.** Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value for kVp and twenty percent for time.

8. **mA/mAs linearity.** The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the

range of forty percent to one hundred percent of the maximum rated:

a. Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product in units of coulombs per kilogram per milliampere second (or milliroentgen per milliampere seconds) obtained at any two consecutive tube current settings shall not differ by more than ten hundredths times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

b. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratio (X_1) of exposure to the indicated milliampere-seconds product, in units of coulombs per kilogram per milliampere second (or milliroentgen per milliampere seconds), obtained at any two consecutive mAs selector settings shall not differ by more than ten hundredths times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provided continuous selection.

c. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than forty-five hundredths millimeters and the other is greater than forty-five hundredths millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

9. **Other requirements:**

a. Transmission limit for image receptor supporting devices used for mammography. For X-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beams through the image receptor support provided with the system will be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image

receptor supporting device does not exceed twenty-five and eight-tenths microcoulomb per kilogram [.01 milliroentgen] for each activation of the tube. Exposure shall be measured with the system operated at the minimum source-image receptor distance for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (milliampere second) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

b. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20-04, 23-20.1-03, 23-20.1-04

33-10-06-07. Intraoral dental radiographic systems. In addition to the requirements of sections 33-10-06-03 and 33-10-06-04, the requirements of this section apply to X-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in section 33-10-06-06. Only systems meeting the requirements of this section shall be used.

1. **Source-to-skin distance.** X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

   a. Eighteen centimeters if operable above fifty kilovolts peak.

   b. Ten centimeters if operable at fifty kilovolts peak only.

2. **Beam limitation.** Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

   a. The X-ray beam, at the minimum source-to-skin distance, shall be containable in a circle having a diameter of no more than seven centimeters.

   b. An open-ended shielded position indicating device shall be used. The shielding shall be equivalent to the requirements of subsection 4 of section 33-10-06-04.

3. **Radiation exposure control.**

a. Exposure initiation.

(1) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

(2) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

b. Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

c. Exposure termination.

(1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

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

(3) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

d. Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of coulombs per kilogram per second [milliroentgen per second], obtained at any two clinically used timer settings shall not differ by more than ten hundredths times their sum.

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average values.

e. Exposure control location and operator protection.

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

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

(a) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph 1 of this subdivision.

(b) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters [6.5 feet] high for operator protection, or means to allow the operator to be at least two and seven-tenths meters [9 feet] from the tube housing assembly while making exposures.

4. **Reproducibility.** When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than five hundredths for any specific combination of selected technique factors.

5. **mA/mAs linearity.** The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rated.

a. Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of coulombs per kilogram per milliampere second (or milliroentgen per milliampere seconds), obtained at any two consecutive tube current settings shall not differ by more than ten hundredths times their sum:

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

where X_1 and X_2 are the average values obtained at any two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

b. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of coulombs per kilogram per milliampere second (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than ten hundredths times their sum:

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

where X_1 and X_2 are the average values obtained by any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

c. Measuring compliance. Determination of compliance shall be based on ten exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than forty-five hundredths millimeters and the other is greater than forty-five hundredths millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

6. **Accuracy.** Deviation of technique factors from values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value for kVp and twenty percent for time.

7. **kVp limitations.** Dental X-ray machines with a nominal fixed kVp of less than fifty kVp shall not be used to make diagnostic dental radiographs of humans.

8. **Beam quality.** All dental X-ray systems are subject to the filtration requirements of subdivision a of subsection 5 of section 33-10-06-04.

9. **Administrative controls.**

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

   b. The tube housing and the position indicating device shall not be handheld during an exposure.

   c. The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subdivision a of subsection 2 of this section.

   d. Dental fluoroscopy without image intensification shall not be used.

10. **Structural shielding requirements** (see appendix C).

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

33-10-06-08. Therapeutic X-ray systems of less than one megaelectronvolt (MeV).

1. **Equipment requirements.**

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

      (1) Contact therapy systems. Leakage radiation shall not exceed twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] per hour at five centimeters from the surface of the tube housing assembly.

      (2) Zero - one hundred fifty kilovolts peak systems. Systems which are manufactured or installed prior to October 1, 1982, shall have a leakage radiation which does not exceed two hundred fifty-eight thousandths millicoulomb per kilogram [1 roentgen] in one hour at one meter from the source.

      (3) Zero - one hundred fifty kilovolts peak systems. Systems which are manufactured on or after October 1, 1982, shall have a leakage radiation which does not exceed twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] in one hour at one meter from the source.

      (4) One hundred fifty-one - nine hundred ninety-nine kilovolts peak systems. The leakage radiation shall not exceed two hundred fifty-eight thousandths millicoulomb per kilogram [1 roentgen] in one hour at one meter from source except systems that operate in excess of five hundred kilovolts peak may have a leakage radiation at one meter from the source not to exceed one-tenth percent of the useful beam one meter from the source.

   b. Permanent beam-limiting devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.

   c. Removable and adjustable beam-limiting devices.

      (1) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by the useful devices, transmit not more than one percent of the beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful

beam to shape the useful beam to the individual patient.

(2) Adjustable beam-limiting devices installed after October 1, 1982, shall meet the requirements of paragraph 1 of this subdivision.

(3) Adjustable beam-limiting devices installed before October 1, 1982, shall, for the portion of the X-ray beam to be blocked by these devices, transmit not more than five percent of the original X-ray beam at the maximum kilovoltage and maximum treatment filter.

d. Filter system. The filter system shall be so designed that:

(1) The filters cannot be accidentally displaced at any possible tube orientation;

(2) The radiation at five centimeters from the filter insertion slot opening does not exceed seven and seventy-four hundredths millicoulomb per kilogram [30 roentgens] per hour under any operating conditions; and

(3) Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

e. Tube immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.

f. Focal spot (actual) marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot (actual) to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

g. Beam block. Contact therapy tube housing assemblies shall have a removable shield of at least five-tenths millimeter lead equivalency at one hundred kilovolts peak that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

h. Beam monitor system. Systems of greater than one hundred fifty kilovolts peak manufactured after October 1, 1982, shall be provided with a beam monitor system which:

(1) Shall have the detector of the monitor system interlocked to prevent incorrect positioning in the useful beam;

(2) Shall not allow irradiation until a preselected number of roentgens has been made at the treatment control panel;

(3) Shall independently terminate irradiation when the preselection number of roentgens has been reached;

(4) Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

(5) Shall have a display at the control panel from which the dose at a reference point in the treatment volume can be calculated;

(6) Shall have a control panel display which maintains the reading until intentionally reset to zero; and

(7) Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

i. Timer.

(1) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(3) The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.

(4) The timer shall permit accurate presetting and determination of exposure times as short as one second.

(5) The timer shall not permit an exposure if set at zero.

(6) The timer shall not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

j. Control panel functions. The control panel, in addition to the displays required in other requirements of this section shall have:

(1) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

(2) An indication of whether X-rays are being produced;

(3) Means for indicating kilovolts and X-ray tube current;

(4) The means for terminating an exposure at any time;

(5) A locking device which will prevent unauthorized use of the X-ray system; and

(6) For X-ray equipment manufactured after October 1, 1982, a positive display of specific filters in the beam.

k. Multiple tubes. When a control panel may energize more than one X-ray tube:

(1) It shall be possible to activate only one X-ray tube any time;

(2) There shall be an indication at the control panel identifying which X-ray tube is energized; and

(3) There shall be an indication at the tube housing assembly when that tube is energized.

l. Source-to-skin distance. There shall be means of determining the source-to-skin distance to within one centimeter.

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

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

(2) An indication of shutter position shall appear at the control panel.

n. Low filtration X-ray tubes. Each X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

2. **Facility design requirements for systems capable of operating above fifty kilovolts peak.**

a. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

b. Viewing systems.

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

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

c. Additional requirements for X-ray systems capable of operation above one hundred fifty kilovolts peak.

(1) All protective barriers must be fixed except for entrance doors or beam interceptors.

(2) The control panel shall be outside the treatment room.

(3) Entrance interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(4) When any door referred to in paragraph 3 of this subdivision is opened while the X-ray tube is activated, the radiation exposure at a distance of one meter from the source must be reduced to less than twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] per hour.

3. **Surveys, calibrations, spot checks, and operating procedures.**

a. Surveys.

(1) All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the department within thirty days of receipt of the report.

(3) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of this article.

b. Calibration.

(1) The calibration of an X-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.

(2) The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.

(3) Calibration of the radiation output of an X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The instrument shall have been calibrated within the preceding two years.

(4) The calibrations must be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of five percent.

(5) The calibration of the X-ray system shall include, but not be limited to, the following determinations:

(a) Verification that the X-ray system is operating in compliance with the design specifications.

(b) The exposure rates for each combination of field size, technique factors, filter, and treatment distance used.

(c) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present.

(d) An evaluation of the uniformity of the largest radiation field used.

(6) Records of calibration shall be maintained by the registrant for five years after completion of the calibration.

(7) A copy of the most recent X-ray system calibration shall be available at or in the area of the control panel.

c. Spot checks. Spot checks shall be performed on X-ray systems capable of operation at greater than one hundred fifty kilovolts peak. Such spot checks shall meet the following requirements:

(1) The spot check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedures shall be submitted to the department prior to its implementation.

(2) If a qualified expert does not perform the spot check measurement, the results of the spot check measurements shall be reviewed by a qualified expert within fifteen days.

(3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed. The spot check procedures shall specify that the spot check shall be performed during the calibration specified in subdivision b of subsection 3 of section 33-10-06-08. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in subdivision b of subsection 3 of section 33-10-06-08 shall be stated.

(4) The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.

(5) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot check procedures, the system shall be recalibrated as required in subdivision b of subsection 3 of section 33-10-06-08.

(6) Records of spot check measurements shall be maintained by the registrant for two years after completion of the spot check measurements and any necessary corrective actions.

(7) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 3 of section 33-10-06-08 or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

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

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

(3) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed fifty kilovolts peak. In such cases, the holder shall wear protective gloves and apron of not less than five-tenths millimeter lead equivalency at one hundred kilovolts peak.

(4) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of section 33-10-04.1-06. No individual other than the patient shall be in the treatment room during exposures when the kilovolts peak exceeds one hundred fifty.

(5) The X-ray system shall not be used in the administration of radiation therapy unless the requirements of subdivision b of this subsection and paragraph 4 of subdivision c have been met.

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

33-10-06-09. X-ray and electron therapy systems with energies of one megaelectronvolt (MeV) and above. Chapter 33-10-09 except subdivisions c and d of subsection 7 of section 33-10-09-03 shall apply to medical facilities using therapy systems with energies one megaelectronvolt and above.

1. **Definitions.** In addition to the definitions provided in section 33-10-06-02, the following definitions are applicable to this section.

   a. "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam-limiting device.

   b. "Beam scattering filter" means a filter used in order to scatter a beam of electrons.

   c. "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

   d. "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

   e. "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

   f. "Existing equipment" means therapy systems subject to this section which were manufactured on or before January 1, 1985.

   g. "Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

   h. "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the fifty percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

   i. "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

   j. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

   k. "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

l. "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

m. "New equipment" means systems subject to this section which were manufactured after January 1, 1985.

n. "Normal treatment distance" means:

(1) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) For X-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

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

p. "Shadow tray" means a device attached to the radiation head to support auxiliary beam-limiting material.

q. "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and patient during radiation.

r. "Target" means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

s. "Virtual source" means a point from which radiation appears to originate.

2. **Requirements for equipment.**

a. Leakage radiation to the patient area.

(1) New equipment shall meet the following requirements:

(a) For all operating conditions producing maximum leakage, the absorbed dose in rads [grays] due to leakage radiation, including X-rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or the normal treatment distance and outside the maximum useful beam, shall not exceed one-tenth percent of the maximum absorbed dose in rads [grays] of the

unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters.

(b) For each system the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subparagraph a for specified operation conditions. Records on leakage radiation shall be maintained at the installation for inspection by the department.

(2) Existing equipment shall meet the following requirements:

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

(b) For each system, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subparagraph a of this paragraph for specified operating conditions. Records on radiation leakage shall be maintained at the installation for inspection by the department.

b. Leakage radiation outside the patient area for new equipment.

(1) The absorbed dose in grays [rads] due to leakage radiation, except in the area specified in subparagraph a of paragraph 1 of subdivision a, when measured at any point one meter from the path of

charged particle, before the charged particle strikes the target or window, may not exceed one-tenth percent for X-ray leakage nor five-hundredths percent for neutron leakage of the maximum absorbed dose in grays [rads] of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in subparagraph a of paragraph 1 of subdivision a of this subsection.

(2) The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in paragraph 1 of this subdivision for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified. Neutron measurements shall be averaged over an area up to but not exceeding two hundred square centimeters.

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

d. Filters.

(1) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(2) If the absorbed dose rate data required by subdivision p of subsection 2 of section 33-10-06-04 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

(3) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(a) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) A display shall be provided at the treatment control panel showing the filters in use; and

(d) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

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

(1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the value stated in table III. Linear interpolation shall be used for values not stated.

TABLE III

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

(2) Compliance with paragraph 1 of this subdivision shall be determined using:

(a) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

(b) The largest field size available which does not exceed fifteen centimeters by fifteen centimeters; and

(c) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.

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

Table IV

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

(4) Compliance with paragraph 3 of this subdivision shall be determined by measurements made:

(a) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

(b) Using a phantom whose size and placement meet the requirements of paragraph 2 of this subdivision;

(c) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

(d) The largest field size available which does not exceed fifteen centimeters by fifteen centimeters.

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

f. Beam monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

(1) New equipment shall be provided with at least two radiation detectors. The detectors shall be

incorporated into two separate dose monitoring systems.

(2) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

(3) The detectors and system into which the detector is incorporated shall meet the following requirements:

(a) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

(b) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

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

(d) For new equipment, the design of the dose monitoring systems shall assure that:

[1] The malfunctioning of one system does not affect the correct functioning of the second system; and

[2] The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

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

[1] Maintain a reading until intentionally reset to zero;

[2] Have only one scale and no scale multiplying factors;

[3] Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

[4] In the event of power failure, the dose monitoring information required in this

subparagraph displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty-minute period of time.

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

h. Selection and display of dose monitor units.

(1) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(2) After useful beam termination, it shall be necessary to reset the dosimeter display to zero before treatment can be reinitiated.

(3) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(4) For new equipment after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

i. Termination of irradiation by the dose monitoring system or systems during stationary beam therapy.

(1) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(2) If original design of the equipment included a second dose monitoring system, that system must be capable of terminating irradiation when not more than fifteen percent or forty dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring.

(3) For new equipment, a second dose monitoring system must be present. That system must be capable of terminating irradiation when not more than ten percent or twenty-five dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(4) For new equipment, an indicator on the control panel must show which dose monitoring system has terminated irradiation.

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

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

l. Timer.

(1) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and decimals of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(3) For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

(4) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitor systems have not previously terminated irradiation.

m. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

(2) An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(4) An interlock system shall be provided to prevent irradiation with X-rays except to obtain a port film when electron applicators are fitted.

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted.

(6) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

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

(1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

(2) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(3) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

(4) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the X-ray target or electron window deviates by more than twenty percent or three

megaelectron volts, whichever is smaller, from the selected nominal energy.

o. Selection of stationary beam therapy or moving beam therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

(2) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(4) The mode of operation shall be displayed at the treatment control panel.

(5) For new equipment, an interlock system shall be provided to terminate irradiation if:

(a) Movement of the gantry occurs during stationary beam therapy; or

(b) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

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

(a) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than twenty percent from the selected value.

(b) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.

(7) Where the dose monitor system terminates the irradiation in arc therapy, the termination of

irradiation shall be as required by subsection 1 of this section.

p. Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated (the radiation detectors specified in subdivision f of subsection 2 of section 33-10-06-09 may form part of this system). In addition:

(1) The dose monitor unit rate shall be displayed at the treatment control panel.

(2) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be a record maintained by the registrant.

q. Location of virtual source and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

(1) The X-ray target or the virtual source of X-rays.

(2) The electron window or the virtual source of electrons if the system has electron beam capabilities.

r. System checking facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

3. Facility and shielding requirements. In addition to chapter 33-10-04.1, the following design requirements shall apply:

a. Protective barriers. All protective barriers must be fixed except for entrance doors or beam interceptors.

b. Control panel. The control panel must be located outside the treatment room.

c. Viewing systems.

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

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

d. Aural communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

e. Room entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".

f. Entrance interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating exposure by manual action at the control panel.

4. Surveys, calibrations, spot checks, and operating procedures.

a. Surveys.

(1) All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the registrant to the department within thirty days of receipt of the report.

(3) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of this article.

b. Calibrations.

(1) The calibration of systems subject to section 33-10-06-09 shall be performed in accordance with an established calibration protocol acceptable to the department (the calibration protocol published by the American association of physicists in medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the department for concurrence that the protocol is acceptable) before the system is first used for irradiation of patient and thereafter at time intervals which do not exceed twelve months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

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

(3) Calibration radiation measurements required by paragraph 1 must be performed using a dosimetry system:

(a) Having a calibration factor for cobalt-60 gamma rays traceable to a national standard.

(b) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration.

(c) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system.

(d) Which has had constancy checks performed on the system as specified by a radiological physicist.

(4) Calibrations must be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

(5) The calibration of the therapy beam shall include but be not limited to the following determinations:

(a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the sidelight and back-pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths.

(b) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

(c) The uniformity of the radiation field and any dependency upon the direction of the useful beam.

(d) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(e) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

(6) Records of the calibration performed pursuant to paragraph 1 of this subdivision shall be maintained by the registrant for five years after completion of the full calibration.

(7) A copy of the latest calibration performed pursuant to paragraph 1 of this subdivision shall be available in the area of the control panel.

c. Spot checks. Spot checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:

(1) The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the department prior to its implementation.

(2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within fifteen days.

(3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

(4) At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.

(5) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement may not be utilized as a spot check measurement.

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

(7) Whenever a spot check indicates a significant change in operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated as required in subdivision b of subsection 4 of this section.

(8) Records of spot check measurements shall be maintained by the registrant for a period of two years after completion of the spot check measurements and any necessary corrective actions.

(9) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 4 of this section or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

(1) No individual other than the patient shall be in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system shall not be used in the administration of radiation therapy unless the requirements of subdivisions a, b, and c of this subsection have been met.

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

33-10-06-10. Veterinary medicine radiographic installations. Repealed effective May 1, 1998.

33-10-06-11. Computed tomography X-ray systems.

1. **Definitions.** In addition to the definitions provided in sections 33-10-01-04 and 33-10-06-02, the following definitions are applicable to this section:

   a. "Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\,dz$$

   where:

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

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

   b. "Contrast scale" means the change in the linear attenuation coefficient per computed tomography number relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

   where:

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

   c. "CS" (See "Contrast scale").

   d. "CT" means a radiologic imaging technique that produces images of "slices" through a patient's body.

   e. "CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in section 33-10-06-02.

f. "CTDI" (See "Computed tomography dose index").

g. "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

h. "CTN" (See "CT number").

i. "CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant (The constant has a normal value of one thousand when the Houndsfield scale of CTN is used.)
μ_x = Linear attenuation coefficient of the material of interest.
μ_w = Linear attenuation coefficient of water.

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

k. "Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted. (See also "Picture element").

l. "Multiple tomogram system" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

m. "Noise" means the standard deviation of the fluctuations in computed tomography number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

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

where:

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

n. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

o. "Picture element" means an elemental area of a tomogram.

p. "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

q. "Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

r. "Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

s. "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

t. "Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

u. "Single tomogram system" means CT a X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

v. "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

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

2. **Requirements for equipment.**

a. Termination of exposure.

(1) Means must be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination must occur within an interval that limits the total scan time to no more than one hundred ten percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(2) A visible signal must indicate when the X-ray exposure has been terminated through the means required by paragraph 1.

(3) The operator must be able to terminate the X-ray exposure at any time during a scan, or series of scans under computed tomography X-ray system control, of greater than one-half second duration.

b. Tomographic plane indication and alignment.

(1) For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(3) If a device using a light source is used to satisfy paragraph 1 or 2, the light source must provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to five hundred lux.

c. Beam-on and shutter status indicators and control switches.

(1) The computed tomography X-ray control and gantry must provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) Each emergency button or switch must be clearly labeled as to its function.

d. Indication of computed tomography conditions of operation. The computed tomography X-ray system must be designed such that the computed tomography conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of computed tomography conditions of operation must be visible from any position from which scan initiation is possible.

e. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube

port may not exceed that permitted by subsection 3 of section 33-10-06-04.

f. Maximum surface computed tomography dose index identification. The angular position where the maximum surface computed tomography dose index occurs must be identified to allow for reproducible positioning of a computed tomography dosimetry phantom.

g. Additional requirements applicable to computed tomography X-ray systems containing a gantry manufactured after September 3, 1985.

(1) The total error in the indicated location of the tomographic plane or reference plane may not exceed five millimeters.

(2) If the X-ray production period is less than one-half second, the indication of X-ray production must be actuated for at least one-half second. Indicators at or near the gantry must be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The deviation of indicated scan increment versus actual increment may not exceed plus or minus one millimeter with any mass from zero to one hundred kilograms resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or thirty centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(4) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the computed tomography conditions of operation prior to the initiation of another scan.

h. Facility design requirements.

(1) Aural communication. Provision must be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

(a) Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous observation of the patient during irradiation and must be so located that the

operator can observe the patient from the control panel.

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

i. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

(a) All computed tomography X-ray systems installed after March 1, 1992, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys must be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(b) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report must be made available to the department upon request.

(2) Radiation calibrations.

(a) The calibration of the radiation output of the computed tomography X-ray system must be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

(b) The calibration of a computed tomography X-ray system must be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

(c) The calibration of the radiation output of a computed tomography X-ray system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years.

(d) Computed tomography dosimetry phantoms must be used in determining the radiation output of a computed tomography X-ray system. Such phantoms

must meet the following specifications and conditions of use:

[1] Computed tomography dosimetry phantoms must be right circular cylinders of polymethyl methacrylate of density one point nineteen plus or minus point zero one grams per cubic centimeter. The phantoms must be at least fourteen centimeters in length and must have diameters of thirty-two centimeters for testing computed tomography X-ray systems designed to image any section of the body and sixteen centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

[2] Computed tomography dosimetry phantoms must provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation one centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

[3] Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

[4] All dose measurements must be performed with the computed tomography dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(e) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(f) Calibration must meet the following requirements:

[1] The dose profile along the center axis of the computed tomography dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal

tomographic thicknesses can be selected, the dose profile determination must be performed for each available nominal tomographic section thickness.

[2] The computed tomography dose index (For the purpose of determining the computed tomography dose index, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) along the two axes specified in item 2 of subparagraph d must be measured. The computed tomography dosimetry phantom must be oriented so that the measurement point one centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface computed tomography dose index identified. The computed tomography conditions of operation must correspond to typical values used by the registrant.

[3] The spot checks specified in paragraph 3 of subdivision i must be made.

(g) Calibration procedures must be in writing. Records of calibrations performed must be maintained for inspection by the department.

(3) Spot checks.

(a) The spot check procedures must be in writing and must have been developed by a qualified expert.

(b) The spot check procedures must incorporate the use of a computed tomography dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean computed tomography number for water or other reference material.

(c) All spot checks must be included in the calibration required by paragraph 2 and at time intervals and under system conditions specified by a qualified expert.

(d) Spot checks must include acquisition of images obtained with the computed tomography dosimetry phantoms using the same processing mode and

computed tomography conditions of operation as are used to perform calibrations required by paragraph 2 of subdivision i. The images must be retained, until a new calibration is performed, in two forms as follows:

[1] Photographic copies of the images obtained from the image display device; and

[2] Images stored in digital form on a storage medium compatible with the computed tomography X-ray system.

(e) Written records of the spot checks performed shall be maintained for inspection by the department.

(4) Operating procedures.

(a) The computed tomography X-ray system may not be operated except by an individual who has been specifically trained in its operation.

(b) Information must be available at the control panel regarding the operation and calibration of the system. Such information must include the following:

[1] Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

[2] Instructions on the use of the computed tomography dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

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

[4] A current technique chart available at the control panel which specifies for each routine examination the computed tomography conditions of operation and the number of scans per examination.

(c) If the calibration or spot check of the computed tomography X-ray system identifies that a system

operating parameter has exceeded a tolerance established by the qualified expert, use of the computed tomography X-ray system on patients must be limited to those uses permitted by established written instructions of the qualified expert.

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

APPENDIX A
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

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

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

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

   b. Structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room or rooms concerned.

   c. The dimensions of the room or rooms concerned.

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

   e. The make and model of the X-ray equipment and the maximum technique factors.

   f. The type of examinations or treatments which will be performed with the equipment, e.g., dental, orthodontal, chest, gastrointestinal, fluoroscopic, podiatry, fixed therapy, rotational therapy, etc.

2. Information on the anticipated workload of the X-ray systems.

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

History: Amended effective June 1, 1992.

APPENDIX B
MINIMUM DESIGN REQUIREMENTS FOR AN X-RAY MACHINE OPERATOR'S BOOTH

1. Space requirements.

   a. The operator shall be allotted not less than seven and five-tenths square feet [0.697 square meters] of unobstructed floor space in the booth.

   b. The operator's booth may be any geometric configuration with no dimension of less than two feet [0.61 meters].

   c. The space shall be allotted excluding any encumbrance by the console, such as overhang, cables, or other similar encroachments.

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

2. Structural requirements.

   a. The booth walls shall be permanently fixed barriers of at least seven feet [2.13 meters] high.

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

   c. Shielding must be provided to meet the requirements of chapter 33-10-04.1 of these rules.

3. X-ray control placement.

   a. The X-ray control for the system shall be fixed within the booth and:

      (1) Shall be at least forty inches [1.02 meters] from any open edge of the booth wall which is nearest to the examining table.

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

4. Viewing system requirements.

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

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

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door, which allows access to the room, cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

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

(1) The viewing area must be at least one square foot [0.0929 square meters].

(2) The design of the booth must be such that the operator's expected position when viewing the patient and operating the X-ray system is at least eighteen inches [0.457 meters] from the edge of the booth.

(3) The material constituting the window must have the same lead equivalence as that required in the booth's wall in which it is mounted.

c. When the viewing system is by mirrors, the mirrors must be so located as to accomplish the general requirements subdivision a of subsection 4 of appendix B.

d. When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements in subdivision a of appendix B, and

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

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994.

APPENDIX C
STRUCTURAL SHIELDING REQUIREMENTS

1. General requirements.

   a. Each installation must be provided with such primary or secondary barriers as are necessary to assure compliance with sections 33-10-04.1-06 and 33-10-04.1-07. This requirement must be deemed to be met if the thicknesses of such barriers are equivalent to those as computed in accordance with Appendices B, C, and D of the National Council on Radiation Protection and Measurements Report No. 49, "Medical X-Ray and Gamma-Ray Protection For Energies Up to 10 MeV", modified to meet current dose limits.

   b. Lead barriers must be mounted in such manner that they will not sag or cold-flow because of their own weight and shall be protected against mechanical damage.

   c. Joints between different kinds of protective materials must be designed so that the overall protection of the barrier is not impaired.

   d. Joints at the floor and ceiling must be designed so that the overall protection is not impaired.

   e. Windows, window frames, doors, and door frames must have the same lead equivalent as that required of the adjacent wall.

   f. Holes in protective barriers must be covered so that overall attenuation is not impaired.

2. Fluoroscopic X-ray systems. Ordinarily, only secondary barriers are necessary except combined fluoroscopic-radiographic installations.

3. Radiographic systems other than fluoroscopic, dental intraoral, or veterinarian systems:

   a. All wall, floor, and ceiling areas exposed to the useful beam must have primary barriers. Primary barriers in walls must extend to a minimum height of eighty-four inches [2.13 meters] above the floor.

   b. Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier requirements are lower than the secondary requirements.

c. The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

d. A window of lead equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure.

e. For mobile and portable X-ray systems which are used for greater than one week in one location (one room or suite), the requirements of this appendix shall apply.

4. Intraoral dental radiographic systems.

a. Dental rooms containing X-ray machines shall be provided with primary barriers at all areas struck by the useful beam. Consideration shall be given to the attenuation provided by the patient.

b. When dental X-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas.

Note: In many cases, structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.

5. Therapeutic X-ray installations. The structural shielding requirements shall be deemed to be met if the barriers have been designed and constructed in accordance with the National Council on Radiation Protection and Measurements Report No. 49, "Medical X-Ray and Gamma-Ray Protection for Energies Up to 10 MeV", modified to meet current dose limits.

6. Veterinary medicine radiographic installations.

a. All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four inches [2.13 meters] above the floor.

b. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier requirements are lower than the secondary requirements.

APPENDIX D
X-RAY FILM DEVELOPING

Time Temperature Chart

Thermometer Readings (Degrees)			Minimum Developing Times (Minutes)
C		F	
27	-	80	2
		79	2
		78	2 1/2
		77	2 1/2
24	-	76	3
		75	3
		74	3 1/2
		73	3 1/2
22	-	72	4
		71	4
		70	4 1/2
		69	4 1/2
20	-	68	5
		67	5 1/2
		66	5 1/2
		65	6
18	-	64	6 1/2
		63	7
		62	8
		61	8 1/2
16	-	60	9 1/2

Processing of Film

1. Manual processing of film.

   a. Where film is developed manually, processing tanks should be made of mechanically rigid, corrosion resistant material and the temperature of solutions in the tanks shall be maintained within the range of sixteen degrees Celsius to twenty-seven degrees Celsius [60-80 degrees Fahrenheit]. Film shall be developed in accordance with the time-temperature

relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the above time-temperature chart.

b. Devices shall be available which will give all of the following:

(1) The actual temperature of the developer.

(2) An audible or visible signal, after a preset time (in minutes of duration).

2. Automatic processors and other closed processing systems.

a. Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

b. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

c. Preventive maintenance shall be performed on the unit, except for extended periods of nonuse, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer a maintenance schedule shall be established which will preserve good film quality.

d. After a full cleansing of the processor a film shall be exposed to a density of approximately one, with one-half of the film protected exposure. It will be developed and then kept near the unit and daily at least one test film (exposed under techniques identical with those used for the original test film) shall be compared with the original test film to evaluate the adequacy of the unit's developing capability and base fog level.

3. Processing deviations from the requirements of appendix D shall be documented by the registrant in such manner that the requirements are shown to be met

or exceeded (e.g., extended processing, and special rapid chemistry).

4. Other Requirements:

   a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

   b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

   c. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

   d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

   e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

   f. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

   g. Film developing solutions shall be prepared in accordance with the directions given by the

manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

APPENDIX E
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

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

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

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

3. A detailed description of the X-ray examinations proposed in the screening program.

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

5. Any evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert on the X-ray systems to be used in the screening program. The evaluation by the qualified expert shall show that such systems do satisfy all requirements of this article. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the diagnostic X-ray quality control program.

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

9. The qualifications of each individual who will be operating the X-ray systems.

10. The qualifications of the individual who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiographs.

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

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

14. An indication of the frequency of screening and the duration of the entire screening program.

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; May 1, 1998.

APPENDIX F

DETERMINATION OF COMPETENCE

The Department may use interview, observation and/or testing to determine compliance. The following are areas in which an individual shall have expertise for the competent operation of X-ray equipment:

1. Fundamentals of radiation safety.

   a. Characteristics of X-radiation.
   b. Units of radiation dose (mrem).
   c. Hazards of exposure to radiation.
   d. Levels of radiation from sources of radiation.
   e. Methods of controlling radiation dose.

      (1) Working time.
      (2) Working distance.
      (3) Shielding.
      (4) Collimation.
      (5) Filtration.
      (6) Gonad shielding and other patient protection devices.
      (7) Restriction of X-ray beam to the image receptor.
      (8) Grid utilization.
      (9) Utilization of mechanical immobilization device.

2. Familiarization with equipment.

   a. Identification of controls.
   b. Function of each control.
   c. How to use a technique chart.

3. Film processing.

   a. Film speed as related to patient exposure.
   b. Film processing parameters.
   c. Quality assurance program.

4. Emergency procedures.

   a. Termination of exposure in event of automatic timing device failure.

5. Proper use of personnel dosimetry.

    a. Location of dosimeter.
    b. Interpretation of personnel monitoring reports.

6. Anatomy and positioning.

    a. Relevant human anatomy.
    b. Relevant human physiology.
    c. Radiographic positioning.

7. The requirements of pertinent federal and state rules.

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

History: Effective June 1, 1986; amended effective June 1, 1992; May 1, 1998.

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

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 gama 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 administrated 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 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 shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(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, and 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, and 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 subdivisions 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 33-10-07-03.1 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 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 hundred microsieverts [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 technitium], 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 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 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;

(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 subection 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 may 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 may 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 specialities 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 osteopatic 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 followup; 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 shall 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) 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 followup; 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 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 radiosisotope 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