Safety Requirements for Radiographic Equipment - Part 34 (55 FR 843)		
NRC Regulation Section	**State Regulation Section**	**Comments**
34.20	33-10-05-04, subsection 1	
34.21	33-10-05-04, subsection 2	
34.30	33-10-05-04, subsection 11	
34.33	33-10-05-05, subsection 3	
Appendix A (II, C, 3)	Chapter 33-10-05, Appendix A [item 2.c.(4)]	Item 2.c.(4) of Appendix A is currently in draft form, as a part of our current rule revision. The NRC review of our proposed rule was performed on 8/8/2002 (ADAMS ML021840389 and ML022210543)

From Our 1994 Rule Revision

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 28-32-02
Law Implemented: NDCC 28-32-02

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 28-32-02
Law Implemented: NDCC 28-32-02

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 ~~5~~1 of section 33-10-04-0~~2~~7.

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 paragraph 2 of subdivision b of subsection 1 of section 33-10-05-05~~ 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 5~~2~~1 of section 33-10-04-0~~2~~7.

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.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

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: Amended effective October 1, 1982; June 1, 1986; June 1, 1992.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

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 standard N432-1980 "Radiological safety for the design and construction of apparatus for gamma radiography," (published in NBS handbook 136, issued January 1981).

   b. In addition to the requirements specified in subdivision a of this subsection, 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 of this section, 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, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) Each sealed source or source assembly must have attached to it or engraved 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 standard N432 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 standard N432.

(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. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992 must comply with the requirements of this section.

e. All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of this section.

~~1~~2. **Limits on levels of radiation for radiographic exposure devices and storage containers.**

a. Radiographic exposure devices measuring less than four inches [10 centimeters] from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of fifty milliroentgens [1.29×10^{-5} Coulombs per kilogram] per hour at six inches [15 centimeters] from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four inches [10 centimeters] 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 two hundred milliroentgens [5.16×10^{-5} Coulombs per kilogram] per hour at any exterior surface, and ten milliroentgens [2.58×10^{-6} Coulombs per kilogram] per hour at thirty-nine and four-tenths inches [1 meter] 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.

~~2~~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 33-10-05-0~~7~~6. 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.

~~3~~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 ~~subdivision a of~~ subsection ~~5~~3 of section 33-10-04-0~~5~~516 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.

45. 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. Instrumentation required by this subsection must have a range such that two milliroentgens [5.16×10^{-7} coulombs per kilogram] per hour through one roentgen [2.58×10^{-4} coulombs per kilogram] 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.

56. 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 five-thousandths microcurie [185 bequerels] 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 ~~subdivision e~~ 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 microcuries [becquerels] 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 five-thousandths microcurie [185 becquerels] or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with rules of the department. Within five days after obtaining results of the test, the licensee shall file a report with the department describing the equipment involved, the test results, and the corrective action taken.

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

~~6~~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.

~~7~~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.

~~8~~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.

~~9~~10. Permanent radiographic installations. Permanent radiographic installations having high radiation area entrance controls of the type described in ~~subparagraphs b and c of paragraph 2 of subdivision c of subsection 3 of section 33-10-04-03~~ subsection 1 of section 33-10-04-10 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 33-10-04-16 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 33-10-04-16 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.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

~~33-10-05-04.1. 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: Amended effective October 1, 1982; June 1, 1986; June 1, 1992.~~
~~General Authority: NDCC 28-32-02~~
~~Law Implemented: NDCC 28-32-02~~

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, 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, until such individual:

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

      (2) Has provided the department with documentation showing completion of 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 an examination administered by the department or a third party designated by the department after March 1, 1993.

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.

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 two hundred milliroentgens [5.6×10^{-5} coulombs per kilogram] and shall be recharged daily or at the start of each shift. Each badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

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

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

d. If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or thermoluminescent dosimeter must be processed immediately. The individual must not return to work

with sources of radiation until a determination of the radiation exposure has been made.

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

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

g. Each alarm ratemeter must:

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

(2) Be set to give an alarm signal at a preset dose rate of five hundred 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.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

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 ~~paragraph 2 of subdivision c of~~ subsection ~~3~~1 of section 33-10-04-~~03~~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 ~~4~~3 of section 33-10-04-~~03~~13, areas in which radiography is being performed shall be conspicuously posted as required by ~~paragraph 1 of subdivision c of subsection 3 of section 33-10-04-03 and subdivision b of~~ subsection ~~3~~2 of section 33-10-04-~~03~~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 ~~4~~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 ~~2~~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 two hundred milliroentgens [5.16 x 10^{-5} coulombs per kilogram] for each worker; ~~and~~

      (4) An alarm ratemeter set to give an alarm signal at a preset dose rate of five hundred milliroentgens per hour; and

      (~~4~~5) The appropriate barrier ropes and signs.

   b. Industrial radiographic operations must not be performed if any of the items specified in subdivision a of 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 must 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 ~~5~~1 of section 33-10-04-~~02~~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 subparagraph shall be maintained for inspection by the department until disposition is authorized by the department.

(3) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted and recorded in accordance with subsection ~~9~~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 ~~5~~1 of section 33-10-04-~~02~~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.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

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.

Item 2.c.(4) of Appendix A to Chapter 33-10-05 (draft)

APPENDIX A

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

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

1. Fundamentals of radiation safety
    a. Characteristics of radiation
    b. Units of radiation dose (mrem ~~or~~ and sievert) and quantity of radioactivity (curie ~~or~~ and becquerel)
    c. Significance of radiation dose
        (1) Radiation protection standards
        (2) Biological effects of radiation
        (3) Case histories of radiography accidents
    d. Levels of radiation from ~~sources of radiation~~ licensed material
    e. Methods of controlling radiation dose
        (1) Working time
        (2) Working distances
        (3) Shielding
2. Radiation detection instrumentation to be used
    a. Use of radiation survey instruments
        (1) Operation
        (2) Calibration
        (3) Limitations

b. Survey techniques

c. Use of personnel monitoring equipment

(1) ~~Film badges~~ Personnel dosimeters

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

(3) Pocket dosimeters

(4) Other monitoring equipment

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

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

5. Radiographic equipment to be used

a. Remote handling equipment

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

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

d. Operation and control of X-ray equipment

e. Collimators

f. Storage, control and disposal of licensed material

g. Inspection and maintenance of equipment

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

ASNT Certification of Radiographers - Part 34 (56 FR 11504)		
NRC Regulation Section	**State Regulation Section**	**Comments**
34.11(b)(5)	33-10-05-05, subsections 1 and 5	

We recognize the ASNT certification program and offer the CRCPD exam. Our certification requirements are attached and are listed above.

Note: Section 33-10-05-05 is in the process of being revised. The NRC review of our proposed rule was performed on 8/8/2002 (ADAMS ML021840389 and ML022210543).

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:

(continued on next page)

(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.

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

Notification of Incidents - Parts 20, 30, 31, 34, 39, 40, 70 (56 FR 64980)		
NRC Regulation Section	**State Regulation Section**	**Comments**
39.77(b)	33-10-12-09, subsection 1 is equivalent	

33-10-12-09. Notification of incidents, abandonment, and lost sources.

1. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of chapter 33-10-04.1.

2. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

   a. Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations.

   b. Notify the department immediately by telephone and subsequently within thirty days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter must identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

3. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

   a. Advise the well operator of an appropriate method of abandonment, which shall include:

      (1) The immobilization and sealing in place of the radioactive source with a cement plug.

      (2) The setting of a whipstock or other deflection device.

      (3) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by subsection 4.

   b. Notify the department by telephone, facsimile, or overnight express mail giving the circumstances of the loss, and request approval of the proposed abandonment procedures.

   c. File a written report with the department within thirty days of the abandonment. The licensee shall send a copy of the report to:

      North Dakota Industrial Commission
      Oil and Gas Division
      600 East Boulevard
      Bismarck, North Dakota 58505

Quality Management Program and Misadministrations - Part 35 (56 FR 34104)		
NRC Regulation Section	**State Regulation Section**	**Comments**
35.2	33-10-07-01.1	
35.25	33-10-07-04, subsection 5	
35.32	33-10-07-04, subsection 8	
35.33	33-10-07-04, subsection 9	

Note: The attached pages show the changes made in the March 1, 1994 edition of the North Dakota Radiological Health Rules. For the current version of these sections, please refer to the enclosed May 1, 1998 edition of the North Dakota Radiological Health Rules. Also, we are in the process of adopting the new Part 35; the NRC review of our proposed rule was performed on 8/8/2002 (ADAMS ML021840389 and ML022210543).

1993
Rationale
Chapter 33-10-07
Use of Radionuclides in the Healing Arts

Quality Management Program and Misadministrations:

The NRC published their final rule on quality management programs and misadministrations in the Federal Register on July 25, 1991 (56 FR 34104), which became effective on January 27, 1992. The NRC considers adoption of these regulations a matter of compatibility for all agreement states. Agreement states are expected to adopt and implement regulations that are compatible by January 27, 1995.

The purpose of these rules is to help prevent misadministrations from occurring.

Section 33-10-07-01.1: Definitions have been added for diagnostic clinical procedures manual, prescribed dosage, prescribed dose, recordable event, and written directive. The definition of misadministration has been revised.

Subsection 5 of Section 33-10-07-04 adds a requirement that persons who are using, possessing, etc. radioactive material under supervision must be instructed in the licensee's quality management program and must be required to follow the licensee's written radiation safety and quality management procedures.

Subsection 8 of Section 33-10-07-04 contains the main requirements on quality management programs.

Subsection 9 of Section 33-10-07-04 revises our requirements on misadministrations.

Product Licensing Agreements:

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, others 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.
General Authority: NDCC 32-02
Law Implemented: NDCC 28-32-02

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. "As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

   a. Consistent with the purpose for which the licensed activity is undertaken;

   b. Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations; and

   c. In relation to utilization of nuclear energy in the public interest.

3. "Authorized user" means a practitioner of the healing arts who is identified as an authorized user on a department [agreement state, licensing state or United States nuclear regulatory commission] license that authorizes 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.

~~6~~7. "Management" means the chief executive officer or that individual's designee.

~~7~~8. "Medical institution" means an organization in which several medical disciplines are practiced.

~~8~~9. "Medical use" means the intentional internal or external administration of radioactive material, or the

radiation therefrom, to humans in the practice of the healing arts.

~~9~~10. "Misadministration" means the administration of:

~~a. A radiopharmaceutical or radiation from a sealed source other than the one intended;~~

~~b. A radiopharmaceutical or radiation to the wrong patient;~~

~~c. A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;~~

~~d. A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than fifty percent;~~

~~e. A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than ten percent; or~~

~~f. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than ten percent.~~

a. A radiopharmaceutical dosage greater than thirty microcuries [1110 kilobecquerels] of either sodium iodide I-125 or I-131:

(1) Involving the wrong patient 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 thirty microcuries [1110 kilobecquerels].

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

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

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

c. A gamma stereotactic radiosurgery radiation dose:

(1) Involving the wrong patient 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 patient, 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 is thirty percent greater than 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 patient, 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 thirty microcuries [1110 kilobecquerels] of either sodium iodide I-125 or I-131, both:

(1) Involving the wrong patient, wrong radiopharmaceutical, wrong route of

administration, or when the administered dosage differs from the prescribed dosage; and

(2) When the dose to the patient exceeds five rems [50 millisieverts] effective dose equivalent or fifty rems [500 millisieverts] dose equivalent to any individual organ.

~~10~~11. "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

~~11~~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. "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.

14. "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.

15. "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 thirty microcuries [1110 kilobecquerels] 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 fifteen microcuries [555 kilobecquerels];

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

e. A teletherapy radiation dose when the calculated weekly administered dose is fifteen percent greater than 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.

~~12~~6. "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.

~~13~~7. "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

~~14~~9. "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, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in subdivision f of this definition, containing the following information:

a. For any administration of quantities greater than thirty microcuries [1110 kilobecquerels] 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.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

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.

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 permitting anyone, except a visiting authorized user described in subsection 6 of section 33-10-07-04, to work as an authorized user under the license;

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

d. Before receiving radioactive material in excess of the amount 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 licensee shall notify the department in writing within thirty days when an authorized user, radiation safety officer, or teletherapy physicist, permanently discontinues performance of duties under the license.

History: Effective June 1, 1992.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-07-04. Additional Requirements.

1. As low as 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 reasonably achievable in accordance with subsection 2 of section 33-10-04-0~~1~~5.

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 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 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 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 reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

2. Radiation safety officer.

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

radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

(a) Authorizing the purchase of radioactive material;

(b) Receiving and opening packages of radioactive material;

(c) Storing radioactive material;

(d) Keeping an inventory record of radioactive material;

(e) Using radioactive material safely;

(f) Taking emergency action if control of radioactive material is lost;

(g) Performing periodic radiation surveys;

(h) Performing checks and calibrations of survey instruments and other safety equipment;

(i) Disposing of radioactive material;

(j) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(k) Keeping a copy of all records and reports required by this article, a copy of this article, a copy of each licensing request and license and amendments, and the written policy and procedures required by this article; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and

consent of management prior to submittal to the department for licensing action; or

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

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

a. The committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

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

(3) To establish a quorum and to conduct business, one-half of the committee's membership must be present, including the radiation safety officer and the management's representative.

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

(a) The date of the meeting;

(b) Members present;

(c) Members absent;

(d) Summary of deliberations and discussions;

(e) Recommended actions and the numerical results of all ballots; and

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

(5) The committee shall provide each member with a copy of the meeting minutes, and retain one

copy until the department authorizes its disposition.

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

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

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

(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 hours 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.

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 ~~radiation safety officer~~ licensee; and

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

6. **Visiting authorized user.**

a. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation safety committee;

(2) The licensee has a copy of an agreement state, licensing state, or United States nuclear regulatory commission license that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by an agreement state, licensing state, or United States nuclear regulatory commission license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in subdivision a.

c. A licensee shall retain copies of the records specified in subdivision a for five years from the date of the last visit.

7. **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.

~~8. Records and reports of misadministrations.~~

~~a. When a misadministration involves any therapy procedure, the licensee shall notify the department. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within twenty-four hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within twenty-four hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee may not delay medical care for the patient because of this.~~

~~b. Within fifteen days after an initial therapy misadministration report to the department, the licensee shall report, in writing, to the department and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either was previously notified by the licensee as required by subdivision a. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report may not include the patient's name or other information that could lead to identification of the patient.~~

~~c. When a misadministration involves a diagnostic procedure, the radiation safety officer shall promptly investigate its cause, make a record for department review, and retain the record as directed in subdivision d. The licensee shall also notify the referring physician and the department in writing on NRC form 473 "diagnostic misadministration report" within fifteen days if the misadministration involved the use of radioactive material not intended for medical use, administration of dosage five-fold different from the intended dosage, or administration of radioactive material such that the patient is likely to receive an organ dose greater than two rems [0.02 Sv] or a whole body dose greater than five hundred millirems [5 mSv]. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.~~

~~d. Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient, and the patient's referring physician, the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.~~

~~e. Aside from the notification requirement, nothing in subdivisions a through d shall affect any rights or duties of licensees, and physicians in relation to each other, patients, or responsible relatives or guardians.~~

8. Quality management program.

a. Each applicant or licensee under this part, 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 thirty microcuries [1110 kilobecquerels] 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 identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in

accordance with the respective written directives;

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

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

b. The licensee shall:

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

(a) A representative sample of patient administrations,

(b) All recordable events, and

(c) All misadministrations

to verify compliance with all aspects of the quality management program (these reviews shall be conducted at intervals no greater than 12 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.

9. 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 patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this subsection), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The licensee shall notify the referring physician and also notify the patient 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 patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within twenty-four hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within fifteen days after discovery of the misadministration, a written report to the patient 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 patient, 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 patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

c. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

~~9~~10. Suppliers. A licensee shall use for medical use only:

Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted Areas and Spill Sites] - Parts 30,40 (58 FR 39628)		
NRC Regulation Section	**State Regulation Section**	**Comments**
30.35	33-10-03-05, subsection 14	
30.36	33-10-03-05, subsection 8	

33-10-03-05, subsection 14

Note: These pages show the changes made in the March 1, 1994 edition of the North Dakota Radiological Health Rules. This subsection has been revised since 1994. For the current version of this subsection, please refer to the enclosed May 1, 1998 edition of the North Dakota Radiological Health Rules.

14. **Financial assurance and recordkeeping for decommissioning.**

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than one hundred twenty days and in quantities exceeding one hundred thousand times the applicable quantities set forth in schedule F of this chapter shall submit a decommissioning funding plan as described in subdivision e. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by one hundred thousand is greater than one (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in schedule F of this chapter.

b. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than one hundred twenty days and in quantities specified in subdivision d shall either:

(1) Submit a decommissioning funding plan as described in subdivision e; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by subdivision d using one of the methods described in subdivision f. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of subdivision f is to be submitted to the department.

c. (1) Each holder of a specific license issued on or after January 1, 1994, which is of a type described in subdivision a or b, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subsection.

(2) Each holder of a specific license issued before January 1, 1994, and of a type described in subdivision a shall submit, on or before January 1, 1994, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to seven hundred fifty thousand dollars in accordance with the criteria set forth in this subsection. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before January 1, 1994, and of a type described in subdivision b shall submit, on or before January 1, 1994, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subsection.

d. Table of required amounts of financial assurance for decommissioning by quantity of material.

greater than ten thousand but less than or equal to one hundred thousand times the applicable quantities of schedule F in unsealed form. (For a combination of isotopes, if R, as defined in subdivision a, divided by ten thousand is greater than one but R divided by one hundred thousand is less than or equal to one)	$750,000

greater than one thousand but less than or equal to ten thousand times the applicable quantities of schedule F in unsealed form. (For a combination of isotopes, if R, as defined in subdivision a, divided by one thousand is greater than one but R divided by ten thousand is less than or equal to one) $150,000

greater than ten billion times the applicable quantities of schedule F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in subdivision a, divided by ten billion is greater than one $75,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from subdivision f, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

f. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in schedule G. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subsection. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(a) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless ninety days or more prior to the renewal date, the issuer notifies the department, the beneficiary, and the

licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the department within thirty days after receipt of notification of cancellation.

(b) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the department. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(c) The surety method or insurance must remain in effect until the department has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph 2 of subdivision f.

(4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in subdivision d, and indicating that funds for decommissioning will be obtained when necessary.

g. Each person licensed shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the department. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the department considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the

facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than sixty-five days, a list contained in a single document and updated every two years, of the following:

(a) All areas designated and formerly designated as restricted areas as defined in section 33-10-01-04;

(b) All areas outside of restricted areas that require documentation under paragraph 1 of subdivision g;

(c) All areas outside of restricted areas where current and previous wastes have been buried as documented under subsection 9 of section 33-10-04-15; and

(d) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under subsection 2 of section 33-10-04-14.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

History: Amended effective October 1, 1982, June 1, 1986; June 1, 1992.
General Authority: NDCC 28-32-02

33-10-03-05, subsection 8

Note: These pages show the changes made in the March 1, 1994 edition of the North Dakota Radiological Health Rules. For the current version of this subsection, please refer to the enclosed May 1, 1998 edition of the North Dakota Radiological Health Rules.

8. **Expiration and termination of licenses.**

   a. Except as provided in subdivision b of subsection 9, each specific license shall expire at the end of the specified day, in the month and year stated therein.

   b. Each licensee shall notify the department immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license must

include the required statement and radiation survey report specified in paragraph 1 of subdivision d and a plan for completion of decommissioning if required by license condition or by paragraph 4 of subdivision d.

c. No less than thirty days before the expiration date specified in the license, the licensee shall either:

(1) Submit an application for license renewal under subsection 9; or

(2) Notify the department, in writing, if the licensee decides not to renew the license.

d. (1) If a licensee does not submit an application for license renewal under subsection 9, the licensee shall, on or before the expiration date specified in the license:

(a) Terminate use of radioactive material;

(b) Remove radioactive contamination to the extent practicable;

(c) Properly dispose of radioactive material;

(d) Submit a statement certifying proper disposition of radioactive material using RCP Form 1; and

(e) Submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

[1] Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity, including alpha, in units of transformations per minute (or microcuries) for one hundred square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

[2] Specify the instrumentation used and certify that each instrument was properly calibrated and tested.

(2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no

detectable radioactive contamination was found. The department will notify the licensee, in writing, of the termination of the license.

(3) (a) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the department notifies the licensee, in writing, that the license is terminated. During this time the licensee is subject to the provisions of subdivision e.

(b) In addition to the required statement and radiation survey report submitted under subdivision d, the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

(4) (a) In addition to the information required under subparagraphs d and e of paragraph 1 of subdivision d, the licensee shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the department and could increase potential health and safety impacts to workers or to the public such as in any of the following cases:

[1] Procedures would involve techniques not applied routinely during cleanup or maintenance operations; or

[2] Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; or

[3] Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

[4] Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(b) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

33-10-03-05, subsection 8 (continued)

(c) The proposed decommissioning plan, if required by subparagraph a of paragraph 4 or by license condition, must include:

[1] Description of planned decommissioning activities;

[2] Description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning;

[3] A description of the planned final radiation survey;

[4] The information required in paragraph 3 of subdivision g of subsection 14, and any other information required by subdivision g of subsection 14 that is considered necessary to support the adequacy of the decommissioning plan for approval; and

[5] An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(d) The proposed decommissioning plan will be approved by the department if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

(5) Upon approval of the decommissioning plan by the department, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in subparagraph e of paragraph 1 of subdivision d, shall certify the disposition of accumulated wastes from decommissioning, and shall include a list containing the location and description of all equipment to remain onsite after license termination that was contaminated when final decommissioning was initiated.

e. Each licensee who possesses residual radioactive material under paragraph 3 of subdivision d, following the expiration date specified in the license shall:

(1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee in writing that the license is terminated.

Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards - Part 40
(59 FR 28220)

In our most recent rule revision, which we sent to you in draft form for your review on June 19, 2002, we proposed to adopt all of "Appendix A to Part 40 - Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content". Appendix A to Part 40, and our attached draft rule, include the regulation listed above. Attached is our draft rule for your review.

NRC Regulation Section	State Regulation Section	Comments
Appendix A to Part 40	Schedule D to Chapter 33-10-03	

SCHEDULE D

CRITERIA ~~RELATED~~ RELATING TO THE OPERATION OF URANIUM MILLS AND THE DISPOSITION OF ~~URANIUM MILL~~ TAILINGS OR WASTES PRODUCED BY THE EXTRACTION OR CONCENTRATION OF SOURCE MATERIAL FROM ORES PROCESSED PRIMARILY FOR THEIR SOURCE MATERIAL CONTENT

INTRODUCTION.- As required by subdivision m 1 of subsection 5 of section 33-10-03-05, ~~each~~ every applicant for a license to possess and use source material in conjunction with uranium or thorium milling, or byproduct material at sites formerly associated with such milling, is required to include in a license application proposed specifications relating to milling operations and the disposition of tailings or wastes resulting from such milling activities. This schedule establishes technical, financial, ownership, and long-term site surveillance criteria relating to the siting, operation, decontamination, decommissioning, and reclamation of mills and tailings or waste systems and sites at which such mills and systems are located. As used in this schedule, the term "as low as is reasonably achievable" has the same meaning as in section 33-10-01-04 ~~subsection 2 of section 33-10-04.1-05~~.

In many cases, flexibility is provided in the criteria to allow achieving an optimum tailings disposal program on a site-specific basis. However, in such cases the objectives, technical alternatives, and concerns which must be taken into account in developing a tailings program are identified. As provided by the provisions of paragraph 7 of subdivision 1 of subsection 5 of section 33-10-03-05, ~~A~~applications for licenses must clearly demonstrate how the criteria have been addressed.

The specifications shall be developed considering the expected full capacity of tailings or waste systems and the lifetime of mill operations. Where later expansions of systems or operations may be likely (for example, where large quantities of ore now marginally uneconomical may be stockpiled), the amenability of the disposal system to accommodate increased capacities without degradation in long-term stability and other performance factors shall be evaluated.

~~Detailed programs meeting the technical and financial criteria in this schedule including appropriate supporting data, analyses, and alternatives, shall be developed by existing uranium milling licensees and filed, in connection with license renewal applications or within nine months from the effective date of this schedule whichever occurs first.~~

Licensees or applicants may propose alternatives to the specific requirements in this schedule. The alternative proposals may take into account local or regional conditions, including geology,

topography, hydrology, and meteorology. The department may find that the proposed alternatives meet the department's requirements if the alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with the sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by the requirements of this schedule and the standards promulgated by the United States environmental protection agency in 40 CFR part 192, subparts D and E.

All site-specific licensing decisions based on the criteria in this schedule or alternatives proposed by licensees or applicants will take into account the risk to the public health and safety and the environment with due consideration to the economic costs involved and any other factors the department determines to be appropriate. In implementing this schedule, the department will consider "practicable" and "reasonably achievable" as equivalent terms. Decisions involving these terms will take into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

The following definitions apply to the specified terms as used in this schedule:

"Aquifer" means a geologic formation, group of formations, or part of a formation capable of yielding a significant amount of ground water to wells or springs. Any saturated zone created by uranium or thorium recovery operations would not be considered an aquifer unless the zone is or potentially is (1) hydraulically interconnected to a natural aquifer, (2) capable of discharge to surface water, or (3) reasonably accessible because of migration beyond the vertical projection of the boundary of the land transferred for long-term government ownership and care in accordance with criterion 11 of this schedule.

"As expeditiously as practicable considering technological feasibility", for the purposes of criterion 6A, means as quickly as possible considering: the physical characteristics of the tailings and the site; the limits of "available technology"; the need for consistency with mandatory requirements of other regulatory programs; and "factors beyond the control of the licensee". The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term "available technology".

"Available technology" means technologies and methods for emplacing a final radon barrier on uranium mill tailings piles or

impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry (or one that is reasonably analogous), (such as, by way of illustration only, unreasonable overtime, staffing, or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils, etc.), provided there is reasonable progress toward emplacement of the final radon barrier. To determine grossly excessive costs, the relevant baseline against which cost shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's approved reclamation plan, but costs beyond these estimates shall not automatically be considered grossly excessive.

"Closure" means the activities following operations to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings or waste disposal area.

"Closure plan" means the department-approved plan to accomplish closure.

"Compliance period" begins when the department sets secondary ground-water protection standards and ends when the owner or operator's license is terminated and the site is transferred to the state or federal agency for long-term care.

"Dike" means an embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids or other materials.

"Disposal area" means the area containing byproduct materials to which the requirements of criterion 6 apply.

"Existing portion" means that land surface area of an existing surface impoundment on which significant quantities of uranium or thorium byproduct materials had been placed prior to September 30, 1983.

"Factors beyond the control of the licensee" means factors proximately causing delay in meeting the schedule in the applicable reclamation plan for the timely emplacement of the final radon barrier notwithstanding the good faith efforts of the licensee to complete the barrier in compliance with paragraph (1) of criterion 6A. These factors may include, but are not limited to--

(1) Physical conditions at the site;
(2) Inclement weather or climatic conditions;
(3) An act of God;
(4) An act of war;
(5) A judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements

applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance;

(6) Labor disturbances;

(7) Any modifications, cessation or delay ordered by state, federal, or local agencies;

(8) Delays beyond the time reasonably required in obtaining necessary government permits, licenses, approvals, or consent for activities described in the reclamation plan proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the reclamation plan; and

(9) An act or omission of any third party over whom the licensee has no control.

"Final radon barrier" means the earthen cover (or approved alternative cover) over tailings or waste constructed to comply with criterion 6 of this schedule (excluding erosion protection features).

"Ground water" means water below the land surface in a zone of saturation. For purposes of this schedule, ground water is the water contained within an aquifer as defined above.

"Leachate" means any liquid, including any suspended or dissolved components in the liquid, that has percolated through or drained from the byproduct material.

"Licensed site" means the area contained within the boundary of a location under the control of persons generating or storing byproduct materials under a department license.

"Liner" means a continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment which restricts the downward or lateral escape of byproduct material, hazardous constituents, or leachate.

"Milestone" means an action or event that is required to occur by an enforceable date.

"Operation" means that a uranium or thorium mill tailings pile or impoundment is being used for the continued placement of byproduct material or is in standby status for such placement. A pile or impoundment is in operation from the day that byproduct material is first placed in the pile or impoundment until the day final closure begins.

"Point of compliance" is the site-specific location in the uppermost aquifer where the ground-water protection standard must be met.

"Reclamation plan", for the purposes of criterion 6A, means the plan detailing activities to accomplish reclamation of the tailings or waste disposal area in accordance with the technical criteria of this schedule. The reclamation plan must include a timetable for reclamation milestones that are key to the completion of the final radon barrier including as appropriate, but not limited to, wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and final radon barrier construction. (Reclamation of tailings must also be addressed in the closure plan; the detailed reclamation plan may be incorporated into the closure plan.)

"Surface impoundment" means a natural topographic depression, man-made excavation, or diked area, which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well.

"Uppermost aquifer" means the geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

I. Technical Criteria

CRITERION 1 - The general goal or broad objective in siting and design decisions is permanent isolation of tailings and associated contaminants by minimizing disturbance and dispersion by natural forces, and to do so without ongoing maintenance. For practical reasons, specific siting decisions and design standards must involve finite times (e.g., the longevity design standard in criterion 6). The following site features which will contribute to such a goal or objective must be considered in selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites: ~~In selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites, the following site features, which will determine the extent to which a program meets the broad objective of isolating the tailings and associated contaminants from man and the environment during operations and for thousands of years thereafter without ongoing active maintenance, shall be considered:~~

- remoteness from populated areas;
- hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from ~~useable~~ ground water sources; and

- potential ~~of~~ for minimizing erosion, disturbance, and dispersion by natural forces over the long-term.

The site selection process shall be an optimization to the maximum extent reasonably achievable in terms of these features.

In the selection of disposal sites, primary emphasis shall be given to isolation of tailings or wastes, a matter having long-term impacts, as opposed to consideration only of short-term convenience or benefits, such as minimization of transportation or land acquisition costs. While isolation of tailings will be a function of both site ~~characteristics~~ and engineering design, overriding consideration shall be given to siting features given the long-term nature of the tailings hazards.

Tailings shall be disposed of in a manner ~~such~~ that no active maintenance is required to preserve the condition of the site.

CRITERION 2 - To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material from ~~insite~~ in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote aboveground extraction operations shall ~~preferably~~ be disposed of at existing large mill tailings disposal sites; unless, considering the nature of the wastes, such as their volume and specific activity and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable ~~impractical~~ or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.

CRITERION 3 - The "prime option" for disposal of tailings is placement below grade, either in mines or specially excavated pits (that is, where ~~when~~ the need for any specially constructed retention structure is eliminated). The evaluation of alternative sites and disposal methods performed by mill operators in support of their proposed tailings disposal program (provided in applicants' environmental reports) shall reflect serious consideration of this disposal mode. In some instances, below-grade disposal may not be the most environmentally sound approach, such as might be the case if a ~~high quality~~ ground water formation is relatively close to the surface or not very well isolated by overlying soils and rock. Also, geologic and topographic conditions might make full, below-grade burial impracticable ~~impractical~~; for example, bedrock may be sufficiently near the surface that blasting would be required to excavate a disposal pit at excessive cost, and more suitable alternate sites are not available. Where full below-grade burial is not practicable ~~practical~~, the size of retention structures, and size and steepness of slopes of associated exposed embankments,

shall be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic ~~hydrogeologic~~ conditions at a site. In these cases, it must be demonstrated that an above-grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

CRITERION 4 - The following site and design criteria shall be adhered to whether tailings or wastes are disposed of above or below grade:

(a) Upstream rainfall catchment areas must be minimized to decrease erosion potential and the size of the ~~maximum possible~~ floods which could erode or wash out sections of the tailings disposal area.

(b) Topographic features shall provide good wind protection.

(c) Embankment and cover slopes shall be relatively flat after final stabilization to minimize erosion potential and to provide conservative factors of safety assuring long-term stability. The broad objective should be to contour final slopes to grades which are as close as possible to those which would be provided if tailings were disposed of below grade; this could, for example, lead to slopes of about ten horizontal to one vertical (10h:1v) or less steep. In general, slopes should not be steeper than about 5h:1v. Where steeper slopes are proposed, reasons why a slope less steep than 5h:1v would be impracticable ~~impractical~~ should be provided, and compensating factors and conditions which make such slopes acceptable should be identified.

(d) A full self-sustaining vegetative cover shall be established or rock cover employed to reduce wind and water erosion to negligible levels.

Where a full vegetative cover is not likely to be self-sustaining due to climatic or other conditions, such as in semi-arid and arid regions, rock cover shall be employed on slopes of the impoundment system. The ~~staff~~ department will consider relaxing this requirement for extremely gentle slopes such as those which may exist on the top of the pile.

The following factors shall be considered in establishing the final rock cover design to avoid displacement of rock particles by human and animal traffic or by natural processes, and to preclude undercutting and piping:

- shape, size, composition, gradation of rock particles (excepting bedding material, average particle size shall be at least cobble size or greater);

- rock cover thickness and zoning of particles by size; and

- steepness of underlying slopes.

Individual rock fragments shall be dense, sound, and resistant to abrasion, and shall be free from cracks, seams, and other defects that would tend to unduly increase their destruction by water and frost actions. Weak, friable, or laminated aggregate shall not be used. Shale, rock, laminated with shale, and cherts shall not be used.

Rock covering of slopes may not be required where top covers are very thick (on the order of ~~eighteen~~ ten meters or greater); impoundment slopes are very gentle (on the order of 10h:1v or less); bulk cover materials have inherently favorable erosion resistance characteristics; and there is negligible drainage catchment area upstream of the pile, and there is good wind protection as described in points (a) and (b) of this criterion.

Furthermore, all impoundment surfaces shall be contoured to avoid areas of concentrated surface runoff or abrupt or sharp changes in slope gradient. In addition to rock cover on slopes, areas toward which surface runoff might be directed shall be well protected with substantial rock cover (riprap). In addition to providing for stability of the impoundment system itself, overall stability, erosion potential, and geomorphology of surrounding terrain shall be evaluated to assure that there are no ongoing or potential processes, such as gully erosion, which would lead to impoundment instability.

(e) The impoundment shall not be located near a capable fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand. As used in this criterion, the term "capable fault" has the same meaning as defined in Section III (g) of Appendix A of 10 CFR Part 100. The term "maximum credible earthquake" means that earthquake which would cause the maximum vibratory ground motion based upon an evaluation of earthquake potential considering the regional and local geology and seismology

and specific characteristics of local subsurface material.

(f) The impoundment, where feasible, should be designed to incorporate features which will promote deposition. For example, design features which promote deposition of sediment suspended in any runoff which flows into the impoundment area might be utilized; the object of such a design feature would be to enhance the thickness of cover over time.

CRITERION 5 - ~~Steps shall be taken to reduce seepage of toxic materials into groundwater to the maximum extent reasonably achievable. Any seepage which does occur shall not result in deterioration of existing groundwater supplies from their current or potential use. The following shall be considered to accomplish this:~~

- ~~Installation of low permeability bottom liners (where synthetic liners are used, a leakage detection system shall be installed immediately below the liner to ensure major failures are detected if they occur. This is in addition to the groundwater monitoring program conducted as provided in Criterion 7. Where clay liners are proposed or relatively thin in-site clay soils are to be relied upon for seepage control, tests shall be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests shall be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases, deterioration has been observed to occur rather rapidly after about nine months of exposure).~~

- ~~Mill process design which provides the maximum practical recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.~~

- ~~Dewatering of tailings by process devices or in-situ drainage system. At new sites, tailings shall be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head for seepage, unless tests show tailings are not amenable to such a system. Where in-situ dewatering is to be conducted, the impoundment bottom shall be graded to assure that the drains are at a low point. The drains shall be protected by suitable filter materials to assure that drains remain free running. The~~

drainage system shall also be adequately sized to assure good drainage.

- Neutralization to promote immobilization of toxic substances.

Where groundwater impacts are occurring at an existing site due to seepage, action shall be taken to alleviate conditions that lead to excessive seepage impacts and restore groundwater quality to its potential use before milling operations began to the maximum extent practical. The specific seepage control and groundwater protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications shall be prepared to control installation of seepage control systems. A quality assurance, testing and inspection program, which includes supervision by a qualified engineer or geologist, shall be established to assure that specification is met.

While the primary method of protecting groundwater shall be isolation of tailings and tailings solutions, disposal involving contact with groundwater will be considered provided supporting tests and analysis are presented demonstrating that the proposed disposal and treatment methods will not degrade groundwater from current or potential uses.

Furthermore, steps shall be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils, suitable methods include lining or compaction of ore storage areas.

In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following.

- The chemical and radioactive characteristics of the waste solutions.

- The characteristics of the underlying soil and geologic formations particularly the extent to which they will control transport of contaminants and solutions. This shall include detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations shall be determined.

- This information shall be gathered by borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to usable ground water. The information gathered on boreholes shall include both geologic and geophysical

~~logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits which are of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability shall not be determined on the basis of laboratory analysis of samples alone, a sufficient amount of field testing (e.g., pump tests) shall be conducted to assure actual field properties are adequately understood. Testing shall be conducted to allow estimating chemisorption attenuation properties of underlying soil and rock.~~

~~Location, extent, quality, and capacity of any ground water at and near the site.~~

Criteria 5A-5D and criterion 13 incorporate the basic ground-water protection standards imposed by the United States environmental protection agency in 40 CFR part 192, subparts D and E (48 FR 45926; October 7, 1983) which apply during operations and prior to the end of closure. Ground-water monitoring to comply with these standards is required by criterion 7A.

5A(1)--The primary ground-water protection standard is a design standard for surface impoundments used to manage uranium and thorium byproduct material. Unless exempted under paragraph 5A(3) of this criterion, surface impoundments (except for an existing portion) must have a liner that is designed, constructed, and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil, ground water, or surface water at any time during the active life (including the closure period) of the impoundment. The liner may be constructed of materials that may allow wastes to migrate into the liner (but not into the adjacent subsurface soil, ground water, or surface water) during the active life of the facility, provided that impoundment closure includes removal or decontamination of all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate. For impoundments that will be closed with the liner material left in place, the liner must be constructed of materials that can prevent wastes from migrating into the liner during the active life of the facility.

5A(2)--The liner required by paragraph 5A(1) above must be-

(a) Constructed of materials that have appropriate chemical properties and sufficient strength and thickness to prevent failure due to pressure gradients (including static head and external hydrogeologic forces), physical

contact with the waste or leachate to which they are exposed, climatic conditions, the stress of installation, and the stress of daily operation;

(b) Placed upon a foundation or base capable of providing support to the liner and resistance to pressure gradients above and below the liner to prevent failure of the liner due to settlement, compression, or uplift; and

(c) Installed to cover all surrounding earth likely to be in contact with the wastes or leachate.

5A(3)--The applicant or licensee will be exempted from the requirements of paragraph 5A(1) of this criterion if the department finds, based on a demonstration by the applicant or licensee, that alternate design and operating practices, including the closure plan, together with site characteristics will prevent the migration of any hazardous constituents into ground water or surface water at any future time. In deciding whether to grant an exemption, the department will consider-

(a) The nature and quantity of the wastes;

(b) The proposed alternate design and operation;

(c) The hydrogeologic setting of the facility, including the attenuative capacity and thickness of the liners and soils present between the impoundment and ground water or surface water; and

(d) All other factors which would influence the quality and mobility of the leachate produced and the potential for it to migrate to ground water or surface water.

5A(4)--A surface impoundment must be designed, constructed, maintained, and operated to prevent overtopping resulting from normal or abnormal operations, overfilling, wind and wave actions, rainfall, or run-on; from malfunctions of level controllers, alarms, and other equipment; and from human error.

5A(5)--When dikes are used to form the surface impoundment, the dikes must be designed, constructed, and maintained with sufficient structural integrity to prevent massive failure of the dikes. In ensuring structural integrity, it must not be presumed that the liner system will function without leakage during the active life of the impoundment.

5B(1)--Uranium and thorium byproduct materials must be managed to conform to the following secondary ground-water protection standard:

Hazardous constituents entering the ground water from a licensed site must not exceed the specified concentration limits in the uppermost aquifer beyond the point of compliance during the compliance period. Hazardous constituents are those constituents identified by the department pursuant to paragraph 5B(2) of this criterion. Specified concentration limits are those limits established by the department as indicated in paragraph 5B(5) of this criterion. The department will also establish the point of compliance and compliance period on a site specific basis through license conditions and orders. The objective in selecting the point of compliance is to provide the earliest practicable warning that the impoundment is releasing hazardous constituents to the ground water. The point of compliance must be selected to provide prompt indication of ground-water contamination on the hydraulically downgradient edge of the disposal area. The department shall identify hazardous constituents, establish concentration limits, set the compliance period, and may adjust the point of compliance if needed to accord with developed data and site information as to the flow of ground water or contaminants, when the detection monitoring established under criterion 7A indicates leakage of hazardous constituents from the disposal area.

5B(2)--A constituent becomes a hazardous constituent subject to paragraph 5B(5) only when the constituent meets all three of the following tests:

(a) The constituent is reasonably expected to be in or derived from the byproduct material in the disposal area;

(b) The constituent has been detected in the ground water in the uppermost aquifer; and

(c) The constituent is listed in criterion 13 of this schedule.

5B(3)--Even when constituents meet all three tests in paragraph 5B(2) of this criterion, the department may exclude a detected constituent from the set of hazardous constituents on a site specific basis if it finds that the constituent is not capable of posing a substantial present or potential hazard to human health or the environment. In deciding whether to exclude constituents, the department will consider the following:

(a) Potential adverse effects on ground-water quality, considering--
  (i) The physical and chemical characteristics of the waste in the licensed site, including its potential for migration;
  (ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity of ground water and the direction of ground-water flow;

(iv) The proximity and withdrawal rates of ground-water users;

(v) The current and future uses of ground water in the area;

(vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(vii) The potential for health risks caused by human exposure to waste constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(ix) The persistence and permanence of the potential adverse effects.

(b) Potential adverse effects on hydraulically-connected surface water quality, considering--

(i) The volume and physical and chemical characteristics of the waste in the licensed site;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity and quality of ground water, and the direction of ground-water flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the licensed site to surface waters;

(vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(vii) The existing quality of surface water, including other sources of contamination and the cumulative impact on surface-water quality;

(viii) The potential for health risks caused by human exposure to waste constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(x) The persistence and permanence of the potential adverse effects.

5B(4)--In making any determinations under paragraphs 5B(3) and 5B(6) of this criterion about the use of ground water in the area around the facility, the department will consider any identification of underground sources of drinking water and exempted aquifers made by the United States environmental protection agency or the department.

5B(5)--At the point of compliance, the concentration of a hazardous constituent must not exceed-

(a) The department approved background concentration of that constituent in the ground water;

(b) The respective value given in the table in paragraph 5C if the constituent is listed in the table and if the background level of the constituent is below the value listed; or

(c) An alternate concentration limit established by the department.

5B(6)--Conceptually, background concentrations pose no incremental hazards and the drinking water limits in paragraph 5C state acceptable hazards but these two options may not be practically achievable at a specific site. Alternate concentration limits that present no significant hazard may be proposed by licensees for department consideration. Licensees must provide the basis for any proposed limits including consideration of practicable corrective actions, that limits are as low as reasonably achievable, and information on the factors the department must consider. The department will establish a site specific alternate concentration limit for a hazardous constituent as provided in paragraph 5B(5) of this criterion if it finds that the proposed limit is as low as reasonably achievable, after considering practicable corrective actions, and that the constituent will not pose a substantial present or potential hazard to human health or the environment as long as the alternate concentration limit is not exceeded. In making the present and potential hazard finding, the department will consider the following factors:

(a) Potential adverse effects on ground-water quality, considering--

(i) The physical and chemical characteristics of the waste in the licensed site including its potential for migration;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity of ground water and the direction of ground-water flow;

(iv) The proximity and withdrawal rates of ground-water users;

(v) The current and future uses of ground water in the area;

(vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(vii) The potential for health risks caused by human exposure to waste constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(ix) The persistence and permanence of the potential adverse effects.

(b) Potential adverse effects on hydraulically-connected surface water quality, considering--

(i) The volume and physical and chemical characteristics of the waste in the licensed site;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity and quality of ground water, and the direction of ground-water flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the licensed site to surface waters;

(vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(vii) The existing quality of surface water including other sources of contamination and the cumulative impact on surface water quality;

(viii) The potential for health risks caused by human exposure to waste constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(x) The persistence and permanence of the potential adverse effects.

5C--Maximum Values for Ground-Water Protection

Constituent or property	Maximum concentration
Milligrams per liter:	
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chromium	0.05
Lead	0.05
Mercury	0.002
Selenium	0.01
Silver	0.05
Endrin (1,2,3,4,10,10-hexachloro-1,7 -expoxy-1,4,4a,5, 6,7,8,9a-octahydro-1, 4-endo, endo-5,8-dimethano naphthalene)	0.0002
Lindane (1,2,3,4,5,6-hexachlorocyclohexane, gamma isomer)	0.004

Methoxychlor (1,1,1-Trichloro-2,2-bis (p-methoxyphenylethane))	0.1
Toxaphene ($C_{10}H_{10}Cl_6$, Technical chlorinated camphene, 67-69 percent chlorine)	0.005
2,4-D (2,4-Dichlorophenoxyacetic acid)	0.1
2,4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid)	0.01

Picocuries per liter:	
Combined radium-226 and radium-228	5
Gross alpha-particle activity (excluding radon and uranium when producing uranium byproduct material or radon and thorium when producing thorium byproduct material)	15

5D--If the ground-water protection standards established under paragraph 5B(1) of this criterion are exceeded at a licensed site, a corrective action program must be put into operation as soon as is practicable, and in no event later than eighteen months after the department finds that the standards have been exceeded. The licensee shall submit the proposed corrective action program and supporting rationale for department approval prior to putting the program into operation, unless otherwise directed by the department. The objective of the program is to return hazardous constituent concentration levels in ground water to the concentration limits set as standards. The licensee's proposed program must address removing the hazardous constituents that have entered the ground water at the point of compliance or treating them in place. The program must also address removing or treating in place any hazardous constituents that exceed concentration limits in ground water between the point of compliance and the downgradient facility property boundary. The licensee shall continue corrective action measures to the extent necessary to achieve and maintain compliance with the ground-water protection standard. The department will determine when the licensee may terminate corrective action measures based on data from the ground-water monitoring program and other information that provide reasonable assurance that the ground-water protection standard will not be exceeded.

5E--In developing and conducting ground-water protection programs, applicants and licensees shall also consider the following:

(1) Installation of bottom liners (Where synthetic liners are used, a leakage detection system must be installed immediately below the liner to ensure major failures are detected if they occur. This is in addition to the ground-water monitoring program conducted as provided in criterion 7. Where clay liners are proposed, or relatively thin, in-situ clay soils are to be relied upon

for seepage control, tests must be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests must be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases deterioration has been observed to occur rather rapidly after about nine months of exposure)).

(2) Mill process designs which provide the maximum practicable recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.

(3) Dewatering of tailings by process devices or in-situ drainage systems (At new sites, tailings must be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head of seepage, unless tests show tailings are not amenable to such a system. Where in-situ dewatering is to be conducted, the impoundment bottom must be graded to assure that the drains are at a low point. The drains must be protected by suitable filter materials to assure that drains remain free running. The drainage system must also be adequately sized to assure good drainage).

(4) Neutralization to promote immobilization of hazardous constituents.

5F--Where ground-water impacts are occurring at an existing site due to seepage, action must be taken to alleviate conditions that lead to excessive seepage impacts and restore ground-water quality. The specific seepage control and ground-water protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications must be prepared to control installation of seepage control systems. A quality assurance, testing, and inspection program, which includes supervision by a qualified engineer or scientist, must be established to assure the specifications are met.

5G--In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following:

(1) The chemical and radioactive characteristics of the waste solutions.

(2) The characteristics of the underlying soil and geologic formations particularly as they will control transport of contaminants and solutions. This includes detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations must be determined. This information must be gathered from borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to ground water. The information gathered on boreholes must include both geologic and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability may not be determined on the basis of laboratory analysis of samples alone; a sufficient amount of field testing (e.g., pump tests) must be conducted to assure actual field properties are adequately understood. Testing must be conducted to allow estimating chemi-sorption attenuation properties of underlying soil and rock.

(3) Location, extent, quality, capacity and current uses of any ground water at and near the site.

5H--Steps must be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils; suitable methods include lining or compaction of ore storage areas.

CRITERION 6 - ~~Sufficient earth cover, but not less than three meters, shall be placed over tailings or wastes at the end of milling operations to result in a calculated reduction in surface exhalation of radon emanating from the tailings or wastes to less than two picocuries per square meter per second. In computing required tailings cover thickness, moisture in soils in excess of amounts found normally in similar soils in similar circumstances shall not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer shall not be taken into account in determining the calculated radon exhalation level. If non-soil materials are proposed to reduce tailings covers to less than three meters, it must be demonstrated that such materials will not crack or degrade by differential settlement, weathering, or other mechanism over long-term time intervals. Near surface materials, i.e., within the top three meters, shall not include mine waste or rock that contains elevated levels of radium; soils used for near surface cover must be~

~~essentially the same, as far as radioactivity is concerned, as that of surrounding soils.~~

(1) In disposing of waste byproduct material, licensees shall place an earthen cover (or approved alternative) over tailings or wastes at the end of milling operations and shall close the waste disposal area in accordance with a design[1] which provides reasonable assurance of control of radiological hazards to (i) be effective for one thousand years, to the extent reasonably achievable, and, in any case, for at least two hundred years, and (ii) limit releases of radon-222 from uranium byproduct materials, and radon-220 from thorium byproduct materials, to the atmosphere so as not to exceed an average[2] release rate of twenty picocuries per square meter per second (pCi/m^2s) to the extent practicable throughout the effective design life determined pursuant to (1)(i) of this criterion. In computing required tailings cover thicknesses, moisture in soils in excess of amounts found normally in similar soils in similar circumstances may not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer may not be taken into account in determining the calculated radon exhalation level. If non-soil materials are proposed as cover materials, it must be demonstrated that these materials will not crack or degrade by differential settlement, weathering, or other mechanism, over long-term intervals.

(2) As soon as reasonably achievable after emplacement of the final cover to limit releases of radon-222 from uranium byproduct material and prior to placement of erosion protection barriers or other features necessary for long-term control of the tailings, the licensee shall verify through appropriate testing and analysis that the

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[1] In the case of thorium byproduct materials, the standard applies only to design. Monitoring for radon emissions from thorium byproduct materials after installation of an appropriately designed cover is not required.

[2] This average applies to the entire surface of each disposal area over a period of a least one year, but a period short compared to one hundred years. Radon will come from both byproduct materials and from covering materials. Radon emissions from covering materials should be estimated as part of developing a closure plan for each site. The standard, however, applies only to emissions from byproduct materials to the atmosphere.

design and construction of the final radon barrier is effective in limiting releases of radon-222 to a level not exceeding twenty picocuries per square meter per second averaged over the entire pile or impoundment using the procedures described in 40 CFR part 61, appendix B, method 115, or another method of verification approved by the department as being at least as effective in demonstrating the effectiveness of the final radon barrier.

(3) When phased emplacement of the final radon barrier is included in the applicable reclamation plan, the verification of radon-222 release rates required in paragraph (2) of this criterion must be conducted for each portion of the pile or impoundment as the final radon barrier for that portion is emplaced.

(4) Within ninety days of the completion of all testing and analysis relevant to the required verification in paragraphs (2) and (3) of this criterion, the uranium mill licensee shall report to the department the results detailing the actions taken to verify that levels of release of radon-222 do not exceed twenty picocuries per square meter per second when averaged over the entire pile or impoundment. The licensee shall maintain records until termination of the license documenting the source of input parameters including the results of all measurements on which they are based, the calculations or analytical methods used to derive values for input parameters, and the procedure used to determine compliance. These records shall be kept in a form suitable for transfer to the custodial agency at the time of transfer of the site to the United States department of energy or a state for long-term care if requested.

(5) Near surface cover materials (i.e., within the top three meters) may not include waste or rock that contains elevated levels of radium; soils used for near surface cover must be essentially the same, as far as radioactivity is concerned, as that of surrounding surface soils. This is to ensure that surface radon exhalation is not significantly above background because of the cover material itself.

(6) The design requirements in this criterion for longevity and control of radon releases apply to any portion of a licensed or disposal site unless such portion contains a concentration of radium in land, averaged over areas of one hundred square meters, which, as a result of

byproduct material, does not exceed the background level by more than:

(i) Five picocuries per gram of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over the first fifteen centimeters below the surface, and (ii) fifteen picocuries per gram of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over fifteen-centimeter thick layers more than fifteen centimeters below the surface.

Byproduct material containing concentrations of radionuclides other than radium in soil, and surface activity on remaining structures, must not result in a total effective dose equivalent (TEDE) exceeding the dose from cleanup of radium contaminated soil to the above standard (benchmark dose), and must be at levels which are as low as is reasonably achievable. If more than one residual radionuclide is present in the same one hundred square-meter area, the sum of the ratios for each radionuclide of concentration present to the concentration limit will not exceed "1" (unity). A calculation of the potential peak annual total effective dose equivalent within one thousand years to the average member of the critical group that would result from applying the radium standard (not including radon) on the site must be submitted for approval. The use of decommissioning plans with benchmark doses which exceed one hundred millirems per year, before application of ALARA, requires the approval of the department. This requirement for dose criteria does not apply to sites that have decommissioning plans for soil and structures approved before June 11, 1999.

(7) The licensee shall also address the nonradiological hazards associated with the wastes in planning and implementing closure. The licensee shall ensure that disposal areas are closed in a manner that minimizes the need for further maintenance. To the extent necessary to prevent threats to human health and the environment, the licensee shall control, minimize, or eliminate post-closure escape of nonradiological hazardous constituents, leachate, contaminated rainwater, or waste decomposition products to the ground or surface waters or to the atmosphere.

Criterion 6A--

(1) For impoundments containing uranium byproduct materials, the final radon barrier must be completed as expeditiously as practicable considering technological feasibility after the pile or impoundment ceases operation in accordance with a written, department-approved reclamation plan. (The term "as expeditiously as practicable considering technological feasibility" as specifically defined in the introduction of this schedule includes factors beyond the control of the licensee.) Deadlines for completion of the final radon barrier and, if applicable, the following interim milestones must be established as a condition of the individual license: windblown tailings retrieval and placement on the pile and interim stabilization (including dewatering or the removal of freestanding liquids and recontouring). The placement of erosion protection barriers or other features necessary for long-term control of the tailings must also be completed in a timely manner in accordance with a written, department-approved reclamation plan.

(2) The department may approve a licensee's request to extend the time for performance of milestones related to emplacement of the final radon barrier if, after providing an opportunity for public participation, the department finds that the licensee has adequately demonstrated in the manner required in paragraph (2) of criterion 6 that releases of radon-222 do not exceed an average of twenty picocuries per square meter per second. If the delay is approved on the basis that the radon releases do not exceed twenty picocuries per square meter per second, a verification of radon levels, as required by paragraph (2) of criterion 6, must be made annually during the period of delay. In addition, once the department has established the date in the reclamation plan for the milestone for completion of the final radon barrier, the department may extend that date based on cost if, after providing an opportunity for public participation, the department finds that the licensee is making good faith efforts to emplace the final radon barrier, the delay is consistent with the definition of available technology, and the radon releases caused by the delay will not result in a significant incremental risk to the public health.

(3) The department may authorize by license amendment, upon licensee request, a portion of the impoundment to accept uranium byproduct material or such materials that are similar in physical, chemical, and radiological characteristics to the uranium mill tailings and

associated wastes already in the pile or impoundment, from other sources, during the closure process. No such authorization will be made if it results in a delay or impediment to emplacement of the final radon barrier over the remainder of the impoundment in a manner that will achieve levels of radon-222 releases not exceeding twenty picocuries per square meter per second averaged over the entire impoundment. The verification required in paragraph (2) of criterion 6 may be completed with a portion of the impoundment being used for further disposal if the department makes a final finding that the impoundment will continue to achieve a level of radon-222 releases not exceeding twenty picocuries per square meter per second averaged over the entire impoundment. In this case, after the final radon barrier is complete except for the continuing disposal area, (a) only byproduct material will be authorized for disposal, (b) the disposal will be limited to the specified existing disposal area, and (c) this authorization will only be made after providing opportunity for public participation. Reclamation of the disposal area, as appropriate, must be completed in a timely manner after disposal operations cease in accordance with paragraph (1) of criterion 6; however, these actions are not required to be complete as part of meeting the deadline for final radon barrier construction.

CRITERION 7 - ~~Milling operations shall be conducted so that all airborne effluent releases are reduced to as low as is reasonably achievable. The primary means of accomplishing this shall be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practical measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. Checks shall be made and logged hourly of all parameters, e.g., differential pressure and scrubber water flow rate, which determine the efficiency of yellowcake stack emission control equipment operation. It shall be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency, corrective action shall be taken when performance is outside of prescribed ranges. Effluent control devices shall be operative at all times~~

~~during drying and packaging operations and whenever air is exhausting from the yellowcake stack.~~

~~Drying and packaging operations shall terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions shall be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations shall cease as soon as practical.~~

~~Operations may not be re-started after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All such cessations, corrective actions, and re-starts shall be reported to the department in writing, within ten days of the subsequent re-start.~~

~~To control dusting from tailings, that portion not covered by standing liquids shall be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is not exposed to wind. Consideration shall be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments since this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.~~

At least one full year prior to any major site construction, a preoperational monitoring program must be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program must be conducted to measure or evaluate compliance with applicable standards and rules; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

7A--The licensee shall establish a detection monitoring program needed for the department to set the site-specific ground water protection standards in paragraph 5B(1) of this schedule. For all monitoring under this paragraph the licensee or applicant will propose for department approval as license conditions which constituents are to be monitored on a site specific basis. A detection monitoring program has two purposes. The initial purpose of the program is to detect leakage of hazardous constituents from the disposal area so that the need to set ground water protection

standards is monitored. If leakage is detected, the second purpose of the program is to generate data and information needed for the department to establish the standards under criterion 5B. The data and information must provide a sufficient basis to identify those hazardous constituents which require concentration limit standards and to enable the department to set the limits for those constituents and the compliance period. They may also need to provide the basis for adjustments to the point of compliance. For licenses in effect September 30, 1983, the detection monitoring programs must have been in place by October 1, 1984. For licenses issued after September 30, 1983, the detection monitoring programs must be in place when specified by the department in orders or license conditions. Once ground water protection standards have been established pursuant to paragraph 5B(1), the licensee shall establish and implement a compliance monitoring program. The purpose of the compliance monitoring program is to determine that the hazardous constituent concentrations in ground water continue to comply with the standards set by the department. In conjunction with a corrective action program, the licensee shall establish and implement a corrective action monitoring program. The purpose of the corrective action monitoring program is to demonstrate the effectiveness of the corrective actions. Any monitoring program required by this paragraph may be based on existing monitoring programs to the extent the existing programs can meet the stated objective for the program.

CRITERION 8 - ~~These criteria relating to ownership of tailings and their disposal sites become effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.~~

~~Any uranium or thorium milling license or tailings license shall contain such terms and conditions as the United States nuclear regulatory commission determines necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.~~

~~Title to the byproduct material license pursuant to subdivision m of subsection 5 of section 33-10-03-05 and land, including any interests therein (other than land owned by the United States or by a state) which is used for the disposal of any such byproduct material, or is essential to ensure the long-term stability of such disposal site, shall be transferred to the United States or the state in which such land is located, at the option of such state. In view of the fact that physical isolation must be the primary means of long-term control, and government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests, for example, mineral rights, may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and~~

~~must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either a United States nuclear regulatory commission general or specific license prohibiting the disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the department may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or the state.~~

~~If the United States nuclear regulatory commission subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to the state will not endanger the public health, safety, welfare, or environment, the United States nuclear regulatory commission may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions provided in these criteria. If the United States nuclear regulatory commission permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.~~

~~Material and land transferred to the United States or the state in accordance with this criterion shall be transferred without cost to the United States or the state other than administrative and legal costs incurred in carrying out such transfer.~~

~~The provisions of chapter 33-10-03 respecting transfer of title and custody to land and tailings and waste shall not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for disposal of byproduct material, as defined in section 33-10-01-04, the licensee shall enter into arrangements with the United States nuclear regulatory commission as may be appropriate to assure the long-term surveillance of such lands by the United States.~~

Milling operations must be conducted so that all airborne effluent releases are reduced to levels as low as is reasonably achievable. The primary means of accomplishing this must be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are

reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. During operations and prior to closure, radiation doses from radon emissions from surface impoundments of uranium or thorium byproduct materials must be kept as low as is reasonably achievable.

Checks must be made and logged hourly of all parameters (e.g., differential pressures and scrubber water flow rates) that determine the efficiency of yellowcake stack emission control equipment operation. The licensee shall retain each log as a record for three years after the last entry in the log is made. It must be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action must be taken when performance is outside of prescribed ranges. Effluent control devices must be operative at all times during drying and packaging operations and whenever air is exhausting from the yellowcake stack. Drying and packaging operations must terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions must be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations must cease as soon as practicable. Operations may not be restarted after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All these cessations, corrective actions, and restarts must be reported to the department as indicated in criterion 8A, in writing, within ten days of the subsequent restart.

To control dusting from tailings, that portion not covered by standing liquids must be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is not exposed to wind. Consideration must be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments because this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.

Milling operations producing or involving thorium byproduct material must be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed two hundred fifty microsieverts [twenty five millirems] to the whole body, seven hundred fifty microsieverts [seventy five millirems] to the thyroid, and two hundred fifty microsieverts [twenty five millirems] to any other organ of any member of the public as a

result of exposures to the planned discharge of radioactive materials, radon-220 and its daughters excepted, to the general environment.

Uranium and thorium byproduct materials must be managed so as to conform to the applicable provisions of title 40 of the Code of Federal Regulations, part 440, "Ore Mining and Dressing Point Source Category: Effluent Limitations Guidelines and New Source Performance Standards, subpart C, Uranium, Radium, and Vanadium Ores Subcategory", as codified on January 1, 1983.

Criterion 8A--Daily inspections of tailings or waste retention systems must be conducted by a qualified engineer or scientist and documented. The licensee shall retain the documentation for each daily inspection as a record for three years after the documentation is made. The department must be immediately notified of any failure in a tailings or waste retention system that results in a release of tailings or waste into unrestricted areas, or of any unusual conditions (conditions not contemplated in the design of the retention system) that if not corrected could indicate the potential or lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

II. Financial Criteria

CRITERION 9 - Financial surety arrangements must be established by each mill operator prior to the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the mill and site and for the reclamation of any tailings or waste disposal areas. The amount of funds to be ensured by such surety arrangements must be based on department-approved cost estimates in a department-approved plan for (1) decontamination and decommissioning of mill buildings and the milling site to levels which allow unrestricted use of these areas upon decommissioning, and (2) the reclamation of tailings and waste areas in accordance with technical criteria delineated in section I of this schedule. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. The surety must also cover the payment of the charge for long-term surveillance and control required by criterion 10. In establishing specific surety arrangements, the licensee's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the department may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other federal or state agencies or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the surety which covers the decommissioning and reclamation of the mill, mill

tailings site and associated areas, and the long-term funding charge is clearly identified and committed for use in accomplishing these activities. The licensees's surety mechanism will be reviewed annually by the department to assure, that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability must be retained until final compliance with the reclamation plan is determined.

This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified period of time (e.g., five years) yet which must be automatically renewed unless the surety notifies the beneficiary (the department or the state regulatory agency) and the principal (the licensee) some reasonable time (e.g., ninety days) prior to the renewal date of their intention not to renew. In such a situation the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least sixty days for the regulatory agency to collect.

Proof of forfeiture must not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended, and must be agreed to by all parties. Financial surety arrangements generally acceptable to the department are:

(a) Surety bonds;
(b) Cash deposits;
(c) Certificates of deposits;
(d) Deposits of government securities;
(e) Irrevocable letters or lines of credit; and
(f) Combinations of the above or such other types of arrangements as may be approved by the department. However, self insurance, or any arrangement which essentially constitutes self insurance (e.g., a contract with a state or federal agency), will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

CRITERION 10 - A minimum charge of six hundred eighty thousand dollars (2001 dollars) to cover the costs of long-term surveillance

must be paid by each mill operator to the general treasury of the United States or to an appropriate state agency prior to the termination of a uranium or thorium mill license.

If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in criterion 12 (e.g., if fencing is determined to be necessary), variance in funding requirements may be specified by the department. In any case, the total charge to cover the costs of long-term surveillance must be such that, with an assumed one percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The total charge will be adjusted annually prior to actual payment to recognize inflation. The inflation rate to be used is that indicated by the change in the consumer price index published by the United States department of labor, bureau of labor statistics.

III. Site and Byproduct Material Ownership

CRITERION 11 -

A. These criteria relating to ownership of tailings and their disposal sites became effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.

B. Any uranium or thorium milling license or tailings license must contain such terms and conditions as the department determines necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.

C. Title to the byproduct material licensed under this chapter and land, including any interests therein (other than land owned by the United States or by a state) which is used for the disposal of any such byproduct material, or is essential to ensure the long term stability of such disposal site, must be transferred to the United States or the state in which such land is located, at the option of such state. In view of the fact that physical isolation must be the primary means of long-term control, and government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests (for example, mineral rights) may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either a department general or specific license prohibiting the

disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the department may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or a state.

D. If the department subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to a state will not endanger the public health, safety, welfare, or environment, the department may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions provided in these criteria. If the department permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.

E. Material and land transferred to the United States or a state in accordance with this criterion must be transferred without cost to the United States or a state other than administrative and legal costs incurred in carrying out such transfer.

F. The provisions of this chapter respecting transfer of title and custody to land and tailings and wastes do not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for the disposal of byproduct material, the licensee shall enter into arrangements with the department as may be appropriate to assure the long-term surveillance of such lands by the United States.

IV. Long-Term Site Surveillance

CRITERION 12 - The final disposition of tailings, residual radioactive material, or wastes at milling sites should be such that ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections must be conducted by the government agency responsible for long-term care of the disposal site to confirm its integrity and to determine the need, if any, for maintenance or monitoring. Results of the inspections for all the sites under the licensee's jurisdiction will be reported to the department annually within ninety days of the last site inspection in that calendar year. Any site where unusual damage or disruption is discovered during the inspection, however, will require a preliminary site inspection report to be submitted within sixty days. On the basis of a site specific evaluation, the department

may require more frequent site inspections if necessary due to the features of a particular disposal site. In this case, a preliminary inspection report is required to be submitted within sixty days following each inspection.

V. Hazardous Constituents

CRITERION 13 - Secondary ground-water protection standards required by criterion 5 of this schedule are concentration limits for individual hazardous constituents. The list of constituents in appendix I of 40 CFR part 192 identifies the constituents for which standards must be set and complied with if the specific constituent is reasonably expected to be in or derived from the byproduct material and has been detected in ground water. For purposes of this schedule, the property of gross alpha activity will be treated as if it is a hazardous constituent. Thus, when setting standards under paragraph 5B(5) of criterion 5, the department will also set a limit for gross alpha activity. The department does not consider the list imposed by appendix I of 40 CFR part 192 to be exhaustive and may determine other constituents to be hazardous on a case-by-case basis, independent of those specified by the United States environmental protection agency in appendix I of 40 CFR part 192.

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994.

Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use - Parts 30, 32, 35 (59 FR 61767 and 60 FR 322)		
NRC Regulation Section	**State Regulation Section**	**Comments**
30.4	33-10-01-04, subsection 64	
32.72	33-10-03-05.5.i	
35.2	33-10-07-01.1, subsections 2, 3, 9, 10, 13, 16, and 20	
35.6	33-10-07-04, subsection 10	
35.7	33-10-07-04, subsection 11	
35.11	33-10-07-03.1, subsection 1	
35.12(e)	Not adopted	
35.13(b)	33-10-07-03.1, subsection 2, subdivision b	
35.14	33-10-07-03.1, subsection 3	
35.15	33-10-07-03.1, subsection 4	
35.22	33-10-07-04, subsection 3	
35.25	33-10-07-04, subsection 5	
35.32	33-10-07-04, subsection 7	
35.33	33-10-07-04, subsection 8	
35.49	33-10-07-04, subsection 9	
35.50	33-10-07-05, subsection 2	
35.52	33-10-07-05, subsection 3	
35.53	33-10-07-05, subsection 5	
35.60	33-10-07-05, subsections 8 and 9	
35.75	33-10-07-05, subsection 13	
35.100	33-10-07-06	
35.200	33-10-07-07	

Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use - Parts 30, 32, 35 (59 FR 61767 and 60 FR 322)		
NRC Regulation Section	**State Regulation Section**	**Comments**
35.300	33-10-07-08, subsection 1	
35.310	33-10-07-08, subsection 2	
35.315	33-10-07-08, subsection 3	
35.404	33-10-07-10, subsection 5	
35.406	33-10-07-10, subsection 4	
35.410	33-10-07-10, subsection 2	
35.415	33-10-07-10, subsection 3	
35.610	33-10-07-11, subsection 4	
35.615(d) & (e)	33-10-07-11, subsections 7 and 8	
35.900	33-10-07-12, subsection 1	
35.910	33-10-07-12, subsection 3	
35.920	33-10-07-12, subsection 4	
35.930	33-10-07-12, subsection 5	
35.940	33-10-07-12, subsection 6	
35.950	33-10-07-12, subsection 8	
35.960	33-10-07-12, subsection 9	
35.961	33-10-07-12, subsection 10	
35.972	33-10-07-12, subsection 13	
35.980	33-10-07-12, subsection 15	
35.981	33-10-07-12, subsection 16	

33-10-01-04, subsection 64

medicine programs, universities, industrial radiographers, or small industrial programs. The terms "type A quantity" and "type B quantity" are defined in chapter 33-10-13.

64. "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 as defined in chapter 33-10-07.

~~61~~65. "Member of the public" means any individual except when that individual is receiving an occupational dose.

~~62~~66. "Minor" means an individual less than eighteen years of age.

~~63~~67. "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material, and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

~~64~~68. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material. (Note: For the purpose of meeting the definition of a licensing state by the conference of radiation control program directors, incorporated., naturally occurring or accelerator-produced radioactive material refers only to discrete sources of naturally occurring or accelerator-produced radioactive material. Diffuse sources of naturally occurring or accelerator-produced radioactive material are excluded from consideration by the conference of radiation control program directors, incorporated. for licensing state designation purposes.)

~~65~~69. "Natural radioactivity" means radioactivity of naturally occurring nuclides.

70. "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

~~66~~71. "Nuclear regulatory commission (NRC)" means the United States nuclear regulatory commission or its duly authorized representatives.

33-10-03-05.5.i

i. Manufacture, ~~and distribution of radiopharmaceuticals~~ preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under ~~group licenses~~ chapter 33-10-07.

(1) An application for a specific license to manufacture, ~~and distribute radiopharmaceuticals~~ prepare, or transfer for commercial distribution of radioactive drugs containing radioactive material for use by persons licensed pursuant to this chapter for the uses listed in subsection 1 of section 33-10-07-06, subsection 1 of section 33-10-07-07, or subsection 1 of section 33-10-07-08 will be approved if:

(a) The applicant satisfies the general requirements specified in subsection 2.

(b) The applicant submits evidence that the application is at least one of the following:

[1] ~~The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application approved by the United States food and drug administration or a "Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the United States food and drug administration; or~~ Registered or licensed with the United States food and drug administration as a drug manufacturer;

[2] ~~The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.~~ Registered or licensed with a state agency as a drug manufacturer;

[3] Licensed as a pharmacy by a state board of pharmacy; or

[4] Operating as a nuclear pharmacy within a federal medical institution.

33-10-03-05.5.i (continued)

(c) The applicant submits information on the radionuclide~~,~~; chemical and physical form~~,~~; ~~packaging including~~ the maximum activity per ~~package~~ vial, syringe, generator or other container of the radioactive drug; and the shielding provided by the packaging ~~of the radioactive material which~~ to show it is appropriate for the safe handling and storage of ~~radiopharmaceuticals~~ radioactive drugs by ~~group~~ medical use licensees~~.~~; and

(d) The applicant satisfied the following labeling requirements:

[1] ~~The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the department for distribution to persons licensed pursuant to this chapter for the uses listed in subsection 1 of section 33-10-07-06, subsection 1 of section 33-10-07-07, and subsection 1 of section 33-10-07-08, or under equivalent licenses of the United States nuclear regulatory commission, an agreement state, or a licensing state.~~ A label is affixed to each transport radiation shield whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

[2] ~~The labels, leaflets, or brochures required by this subparagraph are in addition to the labeling required by the United States food~~

~~and drug administration and they may be separate from or, with the approval of the United States food and drug administration, may be combined with the labeling required by the United States food and drug administration.~~ A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensure that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee who is licensed as a pharmacy by the state board of pharmacy or operating as a nuclear pharmacy within the federal medical institution:

(a) May prepare radioactive drugs for medical use, as defined in section 33-10-07-01.1, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in subparagraphs 2 and 3, or an individual under the supervision of an authorized nuclear pharmacist as specified in subsection 5 of section 33-10-07-04.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

[1] This individual qualifies as an authorized nuclear pharmacist as defined in section 33-10-07-01.1,

[2] This individual meets the requirements specified in subsection 13 of section 33-10-07-12 and subdivision b of subsection 15 of section 33-10-07-12 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

33-10-03-05.5.i (continued)

[3] This individual is designated as an authorized nuclear pharmacist in accordance with subparagraph c.

(c) The actions authorized in subparagraphs a and b are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in section 33-10-07-01.1) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the United State nuclear regulatory commission under 10 Code of Federal Regulations part 32.

(e) Shall provide to the department a copy of each individuals certification by the board of pharmaceutical specialties, the United States nuclear regulatory commission or agreement state license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration no later than 30 days after the date that the licensee allows; pursuant to items 1 and 3 of subparagraph 3, the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. 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, beta-emitting or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependents, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

33-10-03-05.5.i (continued)

(4) Nothing in this subdivision relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs.

~~j. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this chapter for the uses listed in subsection 1 of section 33-10-07-07 will be approved if:~~

~~(1) The applicant satisfies the general requirements specified in subsection 2.~~

~~(2) The applicant submits evidence that:~~

~~(a) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application approved by the United States food and drug administration, or a "Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the United States food and drug administration; or~~

~~(b) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.~~

~~(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit.~~

~~(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay.~~

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. "As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:~~

~~a. Consistent with the purpose for which the licensed activity is undertaken;~~

~~b. Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations; and~~

~~c. In relation to utilization of nuclear energy in the public interest.~~

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 ~~practitioner of the healing arts who is identified as an authorized user on a department [agreement state, licensing state or United States nuclear regulatory commission] license that authorizes the medical use of radioactive material.~~ 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 ~~humans in the practice of the healing arts~~ patients or human research subjects under the supervision of an authorized user.

10. "Misadministration" means the administration of:

    a. A radiopharmaceutical dosage greater than ~~thirty microcuries [1110 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131:

        (1) Involving the wrong ~~patient~~ 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 ~~thirty microcuries [1110 kilobecquerels]~~ 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 ~~patient~~ individual, wrong radiopharmaceutical, or wrong route of administration; or

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

c. A gamma stereotactic radiosurgery radiation dose:

(1) Involving the wrong ~~patient~~ 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 ~~patient~~ 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 ~~is~~ exceeds the weekly prescribed dose by thirty percent ~~greater than~~ 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 ~~patient~~ 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 ~~thirty microcuries [1110 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131, both:

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

(2) When the dose to the ~~patient~~ individual exceeds ~~five rems [50 millisieverts]~~ fifty millisieverts [5 rems] effective dose equivalent or ~~fifty rems [500 millisieverts]~~ 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.

~~13~~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.

~~14~~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.

~~15~~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 ~~thirty microcuries [1110 kilobecquerels]~~ 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 ~~fifteen microcuries [555 kilobecquerels]~~ five hundred fifty-five kilobecquerels [15 microcuries];

d. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed

dosage by more than ten percent of the prescribed dosage;

e. A teletherapy radiation dose when the calculated weekly administered dose ~~is~~ exceeds the weekly prescribed dose by fifteen percent ~~greater than~~ 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.

~~16~~17. "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

~~17~~18. "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.

~~18~~19. "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

~~19~~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 ~~thirty microcuries [1110 kilobecquerels]~~ 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.
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 permitting anyone, except a visiting authorized user described in subsection 6 of section 33-10-07-04, to work as an authorized user under the license;~~ Before it 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 receiving radioactive material in excess of the amount authorized on the license;~~ Before it 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 licensee shall notify the department in writing within thirty days when an authorized user, radiation safety officer, or teletherapy physicist, permanently discontinues performance of duties under the license.~~

a. A licensee shall provide to the department a copy of the board certification, the United State 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.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-04. Additional Requirements.

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

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted

areas as low as is reasonably achievable in accordance with subsection 2 of section 33-10-04.1-05.

b. To satisfy the requirement of subdivision a:

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

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

c. The as low as is reasonably achievable program must include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as is reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

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

(1) A commitment by management to keep occupational doses as low as is reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

2. **Radiation safety officer.**

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

(a) Authorizing the purchase of radioactive material;

(b) Receiving and opening packages of radioactive material;

(c) Storing radioactive material;

(d) Keeping an inventory record of radioactive material;

(e) Using radioactive material safely;

(f) Taking emergency action if control of radioactive material is lost;

(g) Performing periodic radiation surveys;

(h) Performing checks and calibrations of survey instruments and other safety equipment;

(i) Disposing of radioactive material;

(j) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(k) Keeping a copy of all records and reports required by this article, a copy of this article, a copy of each licensing request and license and amendments, and the written policy and procedures required by this article; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the department for licensing action; or

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

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

a. The committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

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

(3) To establish a quorum and to conduct business, one-half of the committee's membership must be present, including the radiation safety officer and the management's representative.

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

(a) The date of the meeting;

(b) Members present;

(c) Members absent;

(d) Summary of deliberations and discussions;

(e) Recommended actions and the numerical results of all ballots; and

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

(5) The committee shall provide each member with a copy of the meeting minutes, and retain one

copy until the department authorizes its disposition.

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

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

(2) (a) Review, on the basis of safety and with regard to the training and experience standards of this ~~part~~ 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 <u>or human research subjects</u>.

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.

<u>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</u>

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. **Visiting authorized user.**~~

~~a. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if.~~

~~(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation safety committee;~~

~~(2) The licensee has a copy of an agreement state, licensing state, or United States nuclear regulatory commission license that identifies the visiting authorized user by name as an authorized user for medical use; and~~

~~(3) Only those procedures for which the visiting authorized user is specifically authorized by an agreement state, licensing state, or United States nuclear regulatory commission license are performed by that individual.~~

~~b. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in subdivision a.~~

~~c. A licensee shall retain copies of the records specified in subdivision a for five years from the date of the last visit.~~

~~7~~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.

~~8~~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 ~~thirty microcuries [1110 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131; or

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

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

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

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within twenty-four hours of the oral directive.)

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

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

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

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

b. The licensee shall:

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

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

(b) All recordable events; and

(c) All misadministrations;

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

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

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

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

(1) Assembling the relevant facts including the cause;

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

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

d. The licensee shall retain:

(1) Each written directive; and

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

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

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

program upon issuance of the license by the department.

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

~~9~~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 ~~patient~~ individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the ~~patient~~ individual, or the ~~patient's~~ individual's responsible relative or guardian ~~(this person will be subsequently referred to as "the patient" in this subsection)~~, and if not, why not~~,~~; and if ~~the patient~~ there was ~~notified~~ notification, what information was provided ~~to the patient~~. The report must not include the ~~patient's~~ individual's name or other information that could lead to identification of the ~~patient~~ 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 ~~patient~~ 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 ~~patient~~ individual or that, based on medical judgment, telling the ~~patient~~ individual would be harmful. The licensee is not required to notify the ~~patient~~ individual without first consulting the referring physician. If the referring physician or ~~patient~~ individual receiving the misadministration cannot be reached within twenty-four hours, the licensee shall notify the ~~patient~~ individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the ~~patient~~ individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the ~~patient~~ 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 ~~patient~~ 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 ~~patient~~ 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 ~~patient~~ individual who received the

misadministration, and ~~the patient's~~ that individual's referring physician if applicable), the ~~patient's~~ 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 ~~patient~~ 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, ~~patients~~ to individuals receiving misadministrations, or ~~the patient's~~ to that individual's responsible relatives or guardians.

~~10~~9. **Suppliers for sealed sources or devices for medical use.** A licensee shall use for medical use only:

a. ~~Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent rules of another agreement state, a licensing state or the United States nuclear regulatory commission; and~~ 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. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the United States food and drug administration.~~

~~c~~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.
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 medical use licensee authorized to administer radiopharmaceuticals shall possess a dose~~

~~calibrator and use it to measure the amount of activity administered to each patient.~~ 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 ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] of radium-226 or ~~fifty microcuries [1.85 megabecquerels]~~ 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 ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] for radium-226 and ~~fifty microcuries [1.85 megabecquerels]~~ 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 ~~ten microcuries [370 kilobecquerels]~~

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 ~~ten microcuries [370 kilobecquerels]~~ 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 ~~two~~ 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, ~~the instrument settings,~~ and the ~~signature of the radiation safety officer~~ 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 ~~signature of the radiation safety officer~~ 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 ~~and calibrated activity~~ of the source measured, ~~the activity of the source,~~ the activity measured ~~and the instrument setting~~ for each volume measured, the date of the test, and the ~~signature of the radiation safety officer~~ 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.

~~3~~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 ~~one thousand millirems [10 millisieverts]~~ 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 ~~two~~ three years. The record must include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of subdivisions a, b, and c the licensee may obtain the services of individuals licensed by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by subdivision e must be maintained by the licensee.

~~4~~5. **Assay of radiopharmaceutical dosages.** A licensee shall:

a. ~~Assay, within thirty minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than ten microcuries [370 kilobecquerels] of a photon-emitting radionuclide;~~ Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use.

b. ~~Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of ten microcuries [370 kilobecquerels] or less of a photon-emitting radionuclide to verify that the dosage does not exceed ten microcuries [370 kilobecquerels]; and~~ 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 ~~assays~~ measurements required by subdivision a and b for ~~two~~ 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 ~~assay~~ measurement, or a notation that the total activity is less than ~~ten microcuries [370 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries];

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

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

~~5~~6. **Authorization for calibration and reference sources.** Any person authorized by subsection 1 of section 33-10-07-03 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to chapter 33-10-03 or equivalent provisions of the United States nuclear regulatory commission, agreement state, or licensing state and that do not exceed ~~fifteen millicuries [555 megabecquerels]~~ 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 ~~fifteen millicuries [555 megabecquerels]~~ 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 ~~two hundred microcuries [7.4 megabecquerels]~~ seven thousand four hundred kilobecquerels [200 microcuries] each; and

d. Technetium-99m in individual amounts not to exceed ~~fifty millicuries [1.85 gigabecquerels]~~ one thousand eight hundred fifty megabecquerels [50 millicuries].

~~6~~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 ~~five thousandths microcurie [185 becquerels]~~ 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 ~~one thousandth microcurie [37 becquerels]~~ 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 ~~microcuries [becquerels]~~ 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 ~~five thousandths microcurie [185 becquerels]~~ 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 ~~one hundred microcuries [3.7 megabecquerels]~~ three thousand seven hundred kilobecquerels [100 microcuries] or less of beta or photon-emitting material or ~~ten microcuries [370 kilobecquerels]~~ 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 ~~two~~ 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 ~~millirems [microsieverts]~~ 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.

~~7~~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.

~~8~~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.

~~9~~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.

~~10~~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.

~~11~~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 tenth millirem [1 microsievert]~~ one microsievert [0.1 milliremⁱ] 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 ~~two~~ 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 ~~millirems [microsieverts]~~ microsieverts [millirems] per hour or the removable contamination in each area expressed in ~~disintegrations per minute [becquerels]~~ 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.

~~12~~13. **Release of ~~patients~~ individuals containing radiopharmaceuticals or permanent implants.**

~~a. A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:~~

~~(1) The dose rate from the patient is less than five millirems [50 microsieverts] per hour at a distance of one meter; or~~

~~(2) The activity in the patient is less than thirty millicuries [1.11 gigabecquerels].~~

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].

~~b. A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than five millirems [50 microsieverts] per hour at a distance of one meter.~~

~~13~~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 ~~two~~ 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 ~~millirems [microsieverts]~~ 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.

~~14~~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.

~~15~~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 ~~two~~ 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.
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 ~~radiopharmaceuticals~~ for uptake, dilution, or excretion studies.

1. Use of ~~radiopharmaceuticals~~ unsealed radioactive material for uptake, dilution, or excretion studies.

a. ~~A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:~~

~~(1) Iodine 131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate.~~

~~(2) Iodine 125 as sodium iodide or iodinated human serum albumin (IHSA).~~

~~(3) Cobalt 57 as labeled cyanocobalamin.~~

~~(4) Cobalt 58 as labeled cyanocobalamin.~~

~~(5) Cobalt 60 as labeled cyanocobalamin.~~

~~(6) Chromium 51 as sodium chromate or labeled human serum albumin.~~

~~(7) Iron 59 as citrate.~~

~~(8) Technetium 99m as pertechnetate.~~

~~(9) Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the food and drug administration has accepted a "notice of claimed investigational exemption for a new drug" (IND) or approved a "new drug application" (NDA).~~

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

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

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

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

2. **Possession of survey instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range ~~one tenth millirem [1.0 microsievert]~~ one microsievert [0.1 milliremⅼ per hour to ~~fifty millirems [500 microsieverts]~~ five hundred microsieverts [50 milliremsⅼ 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.
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 ~~radiopharmaceuticals, generators, and reagent kits~~ unsealed radioactive material for imaging and localization studies.

1. **Use of ~~radiopharmaceuticals, generators, and reagent kits~~ 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. ~~A licensee may use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:~~

~~(1) Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate.~~

~~(2) Technetium-99m as pertechnetate.~~

~~(3) Prepared radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:~~

~~(a) Sulfur colloid;~~

~~(b) Pentetate sodium;~~

~~(c) Human serum albumin microspheres;~~

~~(d) Polyphosphate;~~

~~(e) Macroaggregated human serum albumin;~~

~~(f) Etidronate sodium;~~

~~(g) Stannous pyrophosphate;~~

~~(h) Human serum albumin;~~

~~(i) Medronate sodium;~~

~~(j) Glucceptate sodium;~~

~~(k) Oxidronate sodium;~~

~~(l) Disofenin; and~~

~~(m) Succimer.~~

~~(4) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human~~

~~serum albumin, colloidal (macroaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate.~~

~~(5) Iodine 125 as sodium iodide or fibrinogen.~~

~~(6) Chromium 51 as human serum albumin.~~

~~(7) Gold 198 in colloidal form.~~

~~(8) Mercury 197 as chlormerodrin.~~

~~(9) Selenium 75 as selenomethionine.~~

~~(10) Strontium 85 as nitrate.~~

~~(11) Ytterbium 169 as pentetate sodium.~~

~~(12) Gallium 67 as citrate.~~

~~(13) Indium 111 as chloride or DTPA.~~

~~(14) Tin 113/indium 113m generators for the elution of indium 113m as chloride.~~

~~(15) Yttrium 87/strontium 87m generators for the elution of strontium 87m.~~

~~(16) Thallium 201 as chloride.~~

~~(17) Iodine 123 as sodium iodide or iodohippurate.~~

~~(18) Any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which the food and drug administration has accepted a "notice of claimed investigational exemption for a new drug" (IND), approved a "product licensing agreement" (PLA), or approved a "new drug application" (NDA).~~

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. ~~A licensee using radiopharmaceuticals specified in subdivision a for clinical procedures shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.~~ 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.

~~c. A licensee shall elute generators in compliance with subsection 2 and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.~~

~~d. Technetium 99m pentetate as an aerosol for lung function studies is not subject to the restrictions in subdivision b.~~

~~e. Provided the conditions of subsection 3 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the department.~~

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

a. A licensee may not administer a radiopharmaceutical containing more than fifteen hundredths ~~microcurie~~ kilobecquerel of molybdenum-99 per ~~millicurie~~ megabecquerel of technetium-99m [0.15 ~~kilobecquerel~~ microcurie of molybdenum-99 per ~~megabecquerel~~ 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 ~~two~~ three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in ~~millicuries [megabecquerels]~~ megabecquerels [millicuries], the measured activity of molybdenum expressed in ~~microcuries [kilobecquerels]~~ kilobecquerels [microcuries], the ratio of the measures expressed as ~~microcuries of molybdenum per millicurie of technetium~~ [kilobecquerels of molybdenum per megabecquerel of technetium] [microcuries of molybdenum per millicurie of technetium], the date of the test, and the initials of the individual who performed the test.

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

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

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

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

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

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in appendix B of chapter 33-10-04.1. The calculation must be based on the

highest activity of gas handled in a single container and the measured available air exhaust rate.

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

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements must be maintained for ~~two~~ 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 tenth millirem [1 microsievert]~~ one microsievert [0.1 milliremⅼ] per hour to ~~fifty millirems [500 microsieverts]~~ five hundred microsieverts [50 milliremsⅼ] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one millirem [10 microsieverts]~~ ten microsieverts [1 milliremⅼ] per hour to ~~one thousand millirems [10 millisieverts]~~ ten millisieverts [1000 milliremsⅼ] 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.
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 ~~radiopharmaceuticals for therapy~~ unsealed radioactive material for therapeutic administration.

1. **Use of ~~radiopharmaceuticals for therapy~~ unsealed radioactive material for therapeutic administration.** ~~A licensee may use the following prepared radiopharmaceuticals:~~ A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

   a. ~~Iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma.~~ 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. ~~Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases.~~ 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.

   ~~c. Phosphorus 32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.~~

   ~~d. Gold 198 as colloid for intracavitary treatment of malignant effusions.~~

   ~~e. Any radioactive material in a radiopharmaceutical and for a therapeutic use for which the food and drug administration has accepted a "notice of claimed investigational exemption for a new drug" (IND), or approved a "new drug application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.~~

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~~; and~~.

~~(6) Chapter 33-10-10 training requirements.~~

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 ~~two~~ three years.

3. **Safety precautions.**

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with subsection ~~12~~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 ~~two~~ 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) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;~~

(~~7~~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

(~~8~~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 tenth millirem [1 microsievert]~~ one microsievert [0.1 milliremⅼ] per hour to ~~fifty millirems [500 microsieverts]~~ five hundred microsieverts [50 milliremsⅼ] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one millirem [10 microsieverts]~~ ten microsieverts [1 milliremⅼ] per hour to ~~one thousand millirems [10 microsieverts]~~ ten millisieverts [1000 milliremsⅼ] 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.
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 tenth millirem [1 microsievert]~~ one microsievert [0.1 milliremⅼ] per hour to ~~fifty millirems [500 microsieverts]~~ five hundred millisieverts [50 milliremsⅼ] per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one millirem [10 microsieverts]~~ ten microsieverts [1 milliremⅼ] per hour to ~~one thousand millirems [10 microsieverts]~~ ten millisieverts [1000 milliremsⅼ] 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.
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 <u>or human research subject</u> receiving implant therapy. Refresher training must be provided at intervals not to exceed one year.

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

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the radiation safety officer or authorized user if the patient or the human research subject dies or has a medical emergency~~; and~~.

~~(6) Chapter 33-10-10 training requirements.~~

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 ~~two~~ three years.

3. **Safety precautions.**

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

(1) Not place the patient or the human research subject in the same room with a patient or human research subject who is not receiving radiation therapy ~~unless the licensee can demonstrate compliance with the requirement of subdivision a of subsection 1 of section 33-10-04.1-07 at a distance of one meter from the implant~~;

(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 ~~two~~ 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 ~~millirems [microsievert]~~ microsieverts [millirems] per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

~~(5) Provide the patient with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.~~

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. ~~Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify~~ 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 room number of use and patient's name~~ the patient's or the human research subject's name and room number, the time and date ~~they~~ 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 room number of use and patient's name~~ the patient's or the human research subject's name and room number, the time and date ~~they~~ 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 ~~two~~ 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 ~~two~~ 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 ~~millirems [microsieverts]~~ 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-tenth millirem [1 microsievert]~~ one microsievert [0.1 milliremⁱ] per hour to ~~fifty millirems [500 microsievert]~~ five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one millirem [10 microsieverts]~~ ten microsieverts [1 milliremⁱ] per hour to ~~one thousand millirems [10 microsieverts]~~ 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; March 1, 1994.
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 ~~two~~ 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-tenth millirem [1 microsievert]~~ one microsievert [0.1 millirem] per hour to ~~fifty millirems [500 microsieverts]~~ five hundred microsieverts [50 milliremsl] per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one millirem [10 microsieverts]~~ ten microsieverts [1 millirem] per hour to ~~one thousand millirems [10 microsieverts]~~ ten millisieverts [1000 milliremsl] 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 ~~two~~ three years. The record must include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subdivision e.

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

8. **Viewing system.** A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

9. **Dosimetry equipment.**

a. A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(1) The system must have been calibrated by the national institute of standards and technology or by a calibration laboratory accredited by the American association of physicists in medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was

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

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision a. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system must be the same system used to meet the requirement in subdivision a.

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subdivisions a and b the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison

meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American association of physicists in medicine.

10. **Full calibration measurements.**

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

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

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

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

(1) The output within three percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy, constancy, and linearity;

(5) "On-off" error; and

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

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

d. A licensee shall make full calibration measurements required by subsection 1 in accordance with either the procedures recommended by the scientific committee on radiation dosimetry of the American association of physicists in medicine that are described in Physics in Medicine and Biology vol. 16, no. 3, 1971, pp. 379-396, or by task group 21 of the radiation therapy committee of the American association of physicists in medicine that are described in Medical Physics vol. 10, no. 6, 1983, pp. 741-771, and vol. 11, no. 2, 1984, p.213.

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

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

g. A licensee shall maintain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

11. **Periodic spot checks.**

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

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

(1) Timer constancy and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions; and

(6) The difference between the measurement made in paragraph 5 and the anticipated output,

expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

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

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

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

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

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

(1) Electrical interlocks at each teletherapy room entrance;

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

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

h. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee must use the unit until the interlock system is repaired unless specifically authorized by the department.

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

j. A licensee shall maintain a record of each spot check required by subdivisions a and f for ~~two~~ 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 ~~ten millirems [100 microsieverts]~~ one hundred microsieverts [10 millirems] per hour and ~~two millirems [20 microsieverts]~~ 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 ~~millirems [microsieverts]~~ 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 ~~two~~ 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 ~~rems [sieverts]~~ 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.
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 ~~in radiological physics, therapeutic radiological physics, or medical nuclear physics~~;

      (3) American board of nuclear medicine;

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

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

(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 ~~within the previous five years~~ by the American osteopathic board of radiology; ~~or~~

(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 ~~the patients'~~ their case histories to determine ~~patients'~~ their suitability for radionuclide diagnosis, limitations, or contraindications;

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

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

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

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

c. Has successfully completed a six month training program in nuclear medicine as part of a training program that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subdivision b.

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

a. Is certified in:

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

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

(3) Diagnostic radiology or radiology ~~within the previous five years~~ by the American osteopathic board of radiology; ~~or~~

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiopharmaceutical chemistry; and

(e) Radiation biology.

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

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(c) Calculating and safely preparing patient or human research subject dosages;

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

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

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

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

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

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

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

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

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

c. Has successfully completed a six month training program in nuclear medicine that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subdivision b.

5. **Training for therapeutic use of ~~radiopharmaceuticals~~ 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; ~~or~~

(2) The American board of radiology in radiology, therapeutic radiology, or radiation oncology; ~~or~~

(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 ~~with special competence in nuclear radiology~~, therapeutic radiology, or radiation oncology by the American board of radiology;

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

(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

~~b~~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 ~~6~~ 7 of section 33-10-07-05 and subsections 10, 11 and 12 of section 33-10-07-11 under the supervision of a teletherapy physicist during the year of work experience.

11. **Training for experienced authorized users.** Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a department, United States nuclear regulatory commission, agreement state, or licensing state license on April 1, 1987, who perform only those methods of use for which the practitioners were authorized on that date need not comply with the training requirements of this section.

12. **Physician training in a three-month program.** A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the accreditation council for graduate medical education and has successfully completed the program, is exempted from the requirements of subsections 3 and 4.

13. **Recentness of training.** The training and experience specified in this section shall have been obtained within the ~~five~~ seven years preceding the date of application or the individual shall have had continuing education and applicable experience since the required training and experience was completed.

14. **Training for treatment of hyperthyroidism.** Except as provided in subsection 11, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

    a. Eighty hours of classroom and laboratory training that includes:

        (1) Radiation physics and instrumentation;

        (2) Radiation protection;

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

        (4) Radiation biology; and

    b. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.

15. **Training for an authorized nuclear pharmacist.** The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

    a. Has current board certification as a nuclear pharmacist by the board of pharmaceutical specialties; or

b. (1) Has completed seven hundred hours in a structured educational program consisting of both:

(a) Didactic training in the following areas:

[1] Radiation physics and instrumentation;

[2] Radiation protection;

[3] Mathematics pertaining to the use and measurement of radioactivity;

[4] Chemistry of radioactive material for medical use; and

[5] Radiation biology; and

(b) Supervised experience in a nuclear pharmacy involving the following:

[1] Shipping, receiving, and performing related radiation surveys;

[2] Using and performing checks for proper operation of dose calibrators, survey meters, and if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

[3] Calculating, assaying, and safely preparing dosages for patients or human research subjects;

[4] Using administrative controls to avoid mistakes in the administration of radioactive material;

[5] Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

16. **Training for experienced nuclear pharmacists.** A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. The pharmacist who has completed a structured educational program as specified in paragraph 1 of subdivision b of subsection 15 before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (paragraph 2 of subdivision b of subsection 15) and recentness of training (subsection 13) to qualify as an authorized nuclear pharmacist.

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