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VOLUME 1
TABLE OF CONTENTS

Agriculture, Commissioner of	1
Attorney General	105
Audiology and Speech-Language Pathology, Board of Examiners on	115
Banking and Financial Institutions, Department of	119
Department of Health (June, September)	125

TITLE 7
Commissioner of Agriculture

JUNE 1986

STAFF COMMENT: Section 7-02-02-10 contains all new material but is not underscored so as to improve readability.

7-02-02-10. Honeybee tracheal mite infested apiaries.

1. All apiaries determined to be infested with the honeybee tracheal mite, *acarpis woodi*, shall be placed under quarantine by the state bee inspector. The beekeeper will be notified that the apiary is under quarantine, and may be given specified instructions by the state bee inspector concerning the quarantine.
2. If a chemical approved by the environmental protection agency is available, control of the honeybee tracheal mite by chemical will be allowed if the label instructions are followed. The quarantine will be lifted when the mite is no longer detectable.
3. If no approved chemical is available, the beekeeper will be notified that the apiary is under quarantine and that the beekeeper may either remove the bees of the infested apiary from North Dakota within thirty days, under the direction of the state bee inspector, or cause the bees in the infested apiary to be destroyed. If, within thirty days, the beekeeper does not destroy the bees of the infested apiary, the department may immediately cause the bees of the infested apiary to be destroyed. The quarantine will be removed after destruction has been documented to the satisfaction of the department.
4. Any certificates of health issued to a beekeeper whose apiaries are found to be mite infested shall state on the certificate that the bees are known to be infested with the honeybee tracheal mite, unless the bees of the infested apiary

have been destroyed or successfully treated with approved chemicals.

5. For the purposes of this section, if the state bee inspector places a quarantine on apiaries, neither the beekeeper nor any other person may remove any bees from the apiary without the permission of the state bee inspector.
6. When an apiary is placed under quarantine, the beekeeper will be notified of the location of the infested apiary, and the date when the thirty-day period of notice will expire. If an infested apiary is located within two miles [3.22 kilometers] (from the perimeters of each quarter section) of any other registered apiary of another beekeeper, the inspector may order the infested apiary moved to another specified location. If the infested apiary is not moved to the specified location as ordered by the state bee inspector, the department may cause the bees of the infested apiary to be destroyed immediately.
7. For the purposes of this section, after a quarantine has been imposed, a detectable level for the honeybee tracheal mite will be determined by sampling, one sample taken for every fifty colonies, one hundred bees examined in every sample. The presence of any mites in the bees examined shall be considered an infestation. The department reserves the right to change the method of determining a detectable level, if other more appropriate detection methods are developed.

History: Effective June 1, 1986.

General Authority: NDCC 4-12.1-02

Law Implemented: NDCC 4-12.2-16, 4-12.2-18, 4-12.2-19, 4-12.2-21

AUGUST 1986

**ARTICLE 7-03
DAIRY DIVISION**

[Repealed effective August 1, 1986]

STAFF COMMENT: Article 7-03.1 contains all new material but is not underscored so as to improve readability.

**ARTICLE 7-03.1
DAIRY DIVISION**

Chapter	
7-03.1-01	License to Sample, Grade, or Test
7-03.1-02	Requirements for Sampling and Testing
7-03.1-03	Cream Production on the Farm
7-03.1-04	Sediment Testing
7-03.1-05	Cream Station Requirements
7-03.1-06	Manufacturing Farm Inspection Reports
7-03.1-07	Certification Procedures for All North Dakota Dairy Facilities
7-03.1-08	Transfer Procedures for All Dairy Producers
7-03.1-09	Milk and Milk Products Standards of Identity and Quality
7-03.1-10	Standards for the Composition of Milk Products and Certain Nonmilkfat Products
7-03.1-11	Frozen Desserts
7-03.1-12	Sanitation Requirements for Farms Producing Grade A Raw Milk for Pasteurization, Ultrapasteurization, or Aseptic Processing
7-03.1-13	Inspection Requirements for Dairy Manufacturing

- and Processing Plants
- 7-03.1-14 Inspection Criteria for Grade A Plants
- 7-03.1-15 Transportation of Milk and Cream for Manufacturing,
Processing, or Bottling Purposes
- 7-03.1-16 Milk Haulers Licensing
- 7-03.1-17 Transportation of Processed and Manufactured Products
- 7-03.1-18 Branding Cans, Kegs, Barrels, and Receptacles
- 7-03.1-19 Official Butterfat Test Fee
- 7-03.1-20 Labeling of Milk and Milk Products for Retail Sales

**CHAPTER 7-03.1-01
LICENSE TO SAMPLE, GRADE, OR TEST**

- Section
- 7-03.1-01-01 New Licenses
 - 7-03.1-01-02 Relicensing

7-03.1-01-01. New licenses. Each new sampler, grader, or tester applying for license shall first apply to the dairy commissioner. New testers and graders will be issued a temporary permit good for a time period of three months. New samplers will be issued a temporary permit good for a period of six months. During this time frame, a licensed individual or other qualified individual approved by the dairy commissioner must oversee the permitted individual until such a time within the permitted period that the dairy commissioner can administer the appropriate written and practical examination.

History: Effective August 1, 1986.
General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-12

7-03.1-01-02. Relicensing. To be relicensed, samplers, testers, and graders must hold a current license and take any examinations or retraining required by the dairy commissioner when the dairy commissioner reasonably determines it to be necessary.

History: Effective August 1, 1986.
General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-12

**CHAPTER 7-03.1-02
REQUIREMENTS FOR SAMPLING AND TESTING**

- Section
- 7-03.1-02-01 Accepted Tests

7-03.1-02-02	Standardizing Requirements
7-03.1-02-03	Plant Laboratories
7-03.1-02-04	Universal Sampling Plan
7-03.1-02-05	Sample Reporting - Records
7-03.1-02-06	Composite Sampling
7-03.1-02-07	Farm Tank Calibration
7-03.1-02-08	Sampling Equipment
7-03.1-02-09	Sampling Procedures
7-03.1-02-10	Plant Samplers
7-03.1-02-11	Finished Product Sampling Procedures
7-03.1-02-12	Adulterants

7-03.1-02-01. Accepted tests. The following are the accepted tests to be performed on milk samples:

1. Butterfat - Babcock
Milko Tester
Milko Scan
Berwind Multispec
2. Protein - Udy Protein Analyzer
Pro-milk MK II
Milko Scan
Kjeldahl
Berwind Multispec
3. Solids Not Fat - Udy
Milko Scan
Berwind
4. Bacteria - Standard plate count
Direct microscopic clump count
Plate loop
5. Somatic Cell -
Screening: Wisconsin Mastitis Test - Eighteen millimeters
Confirmatory: Direct microscopic somatic cell count
Electronic somatic cell count
Optical somatic cell count
Membrane filter deoxyribonucleic acid
somatic cell count
6. Coliform - Presumptive on violet red bile agar
Confirmed with brilliant green lactose bile broth
Petrofilm method
7. Antibiotic detection -
Screening: Charm, spot test, Penzyme and Delvo P Ampule Test
Confirmatory: Bacillus Stearothermophilus Disc Assay with
Penase Discs or Penzyme for Antibiotics of
the Beta Lactum Group

8. Phosphatase - Scharer Rapid Phosphatase Test, Rapid Colorimetric Phosphatase Method, Rutgers Phosphatase Test
9. Sediment - Mixed sample method or off-the-bottom method
10. Added Water - Thermistor Cryoscope

The dairy commissioner may approve equivalent tests other than those listed above on a case-by-case basis.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-02. Standardizing requirements. All tests required to standardize testing procedures shall conform with the requirements in the latest addition of "The Standard Methods for the Examination of Dairy Products." The results of such tests must be maintained for one year and must be made available to the dairy commissioner upon request.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-03. Plant laboratories. The laboratory utilized for the sampling and testing of dairy products must meet all of the following requirements:

1. A separate room of adequate size to perform required tests and avoid overcrowding.
2. Doors must be self-closing and tight fitting.
3. Walls and ceilings must be smooth, impervious, and a light color.
4. Floors must be smooth and impervious.
5. A level bench or table covered with an impervious material, with ample working space and utilities, must be provided.
6. Lighting must be provided at each work station at a minimum of one hundred foot-candles.
7. A two-compartment sink with hot and cold water must be provided. The sink must be connected to a sanitary sewer system.
8. Adequate ventilation must be provided to maintain temperature at sixty-one to eighty-one degrees Fahrenheit [16 to 27

degrees Celsius]. Laboratories utilizing Levowitz-Weber stain must have a hooded work area with forced air exhaust.

9. Laboratories utilizing sulfuric acid must have a shower, eye washes, eye protection, or other approved safety equipment available.
10. Cabinets for laboratory chemicals and supplies must be provided. All chemicals utilized in the laboratory must be stored in the laboratory or in other approved areas where proper temperature and ventilation can be maintained. All containers must be marked as to contents.
11. Refrigerators shall be available to maintain samples at thirty-two to forty degrees Fahrenheit [0 to 4.4 degrees Celsius].

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-04. Universal sampling plan. A universal sample must be collected every time the milk is picked up at the farm. This universal sample will be an aseptically collected sample that may be used for any and all tests described in this article.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-05. Sample reporting - Records.

1. The results of all raw milk testing done for regulatory purposes by industry laboratories must be reported to the dairy commissioner no later than thirty days after sampling. However, all adulterants in raw producer samples must be reported immediately, and all tests above the maximum levels established by law must be reported to the dairy commissioner weekly. It is the responsibility of the licensed testers to submit all laboratory results.
2. Records on sampling, testing, or grading of milk or cream, used for the purpose of regulatory enforcement or establishing producer pay levels, must be maintained and available to the dairy department for a period of twelve months. These records must include all of the following:
 - a. Producer identification number.
 - b. Date of sampling, testing, or grading.

- c. Type of sampling, testing, or grading procedure used.
 - d. Results of sampling, testing, or grading.
 - e. Name of licensed tester, grader, or sampler conducting the procedure.
3. During the course of investigating a complaint, the plant shall provide access to all quality records which may assist in the investigation.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18, 4-30-37

7-03.1-02-06. Composite sampling. A composite sample used for the testing of butterfat and protein must consist of a minimum of twenty milliliters which has been made up of a representative sample from each delivery of milk or cream to the plant or cream station. A minimum of ten milliliters of milk from each delivery must be included in the composite sample. The composite sample must be maintained at a temperature of thirty-two to forty degrees Fahrenheit [0 to 4.4 degrees Celsius]. A composite sample may not be maintained for more than fifteen days and must be tested within three days after the last addition. A chemical preservative must be added to maintain the integrity of the sample. Approval for the type and concentration of the preservative must be given by the dairy commissioner upon request. If a composite testing program is being used for butterfat or protein determination, a minimum of two deliveries is required. A log is required on all composite samples maintained and available to the dairy department for a period of twelve months. This log must list all of the following:

1. Date.
2. Pickup weight of milk.
3. Producer's identification.
4. Protein or butterfat, or both, result for that composite sample.
5. Name of licensed tester performing the test.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-07. Farm tank calibration. Where a dispute exists between the buyer and seller of raw milk as to the proper calibration of farm bulk milk tanks, the buyer and seller together shall recalibrate the

tank. Documentation of the new calibration must be signed by both the buyer and seller and sent to the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-08. Sampling equipment. Each sample shall have available for use all of the following:

1. Sampling instrument, either:
 - a. Metal dipper with long handle, capacity of ten milliliters or greater, or
 - b. Single service, individually wrapped or presterilized straws.
2. Sample containers which must be:
 - a. Multiuse containers holding a minimum of two ounces. These containers must be sterilized by dry heat and steam and have leakproof closures. Containers and closures must be phenol-free. Multiuse containers may be used for butterfat sampling only.
 - b. Sterile, evacuated, sampling equipment may be used for collecting at least ten milliliter samples.
 - c. Pasterilized polyethylene or other nontoxic plastic containers of adequate size to meet test requirements.
 - d. Single service, nonsterile, leakproof vials for samples of raw milk or cream may be used provided that:
 - (1) Maximum viable bacteria counts in rinse tests of containers do not exceed one per milliliter of capacity.
 - (2) Containers are not toxic and are not bacteriostatic or bactericidal.
 - (3) Closure is designed to be easily opened and closed without contamination.
 - (4) Containers must be of adequate size to meet test requirements.
3. Sanitizing solution (one hundred parts per million chlorine or equivalent). A sanitizing solution is required when a dipper is used in order to maintain the dipper in a sanitized condition.

4. Sanitizer field test kit, used to measure strength of the sanitizing solution.
5. Dial thermometer, accurate within one degree Fahrenheit [0.55 degrees Celsius]. Accuracy must be checked once during a six-month period. The dial thermometer must be calibrated with the use of a certified mercury actuated thermometer. Certification must be obtained through the dairy department. A log of the results of each dial thermometer certified must be kept containing the same information recorded on the dial thermometer. This log must show the certification history of all dial thermometers for which the certification person is responsible for a period of one year. Each of the following must be listed on the dial thermometer:
 - a. Initials of the person calibrating the dial thermometer.
 - b. The date of calibration.
 - c. The date of expiration and some method of identification (owner's name or thermometer number).
6. Waterproof indelible marker to identify samples.
7. Sample case which must be constructed so as to provide adequate space for samples and proper refrigerant to cool and maintain the samples at thirty-two to forty degrees Fahrenheit [0 to 4.4 degrees Celsius]. A rack must be provided to keep samples in an upright position. The neck of sample containers must be kept above the surface of the refrigerant. A proper refrigerant consists of a mixture of ice and water.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-09. Farm samplers for milk. Individuals licensed to sample milk at the farm shall follow all of the procedures listed below in the order listed:

1. Place transfer hose through the hose port.
2. Carry sampler transfer instrument and sample container into milkroom in an aseptic manner. Single use sample transfer instruments stored in the milkroom must be stored within a closed original container and protected from moisture and contamination.
3. Wash or rinse, or both, and sanitize leaky farm bulk tank valves.

4. Place a sani-guide disk or equivalent in the transfer hose if used and connect milk transfer hose to farm bulk tank valve.
5. Wash and dry hands.
6. Smell milk through farm tank porthole.
7. Observe milk in a quiescent state with the lid open and adequate lighting available. If appearance or smell of the milk in the farm bulk tank leads the sampler to doubt its quality, take a sample and measurement of volume. Contact the receiving plant for additional instructions.
8. Dry measuring rod with an unused single-service paper towel. Seat stick and read with milk in a quiescent state. Record stick reading.
 - a. For farm tanks with external measuring tubes, the milk in the tube after reading must be discharged in a manner not to be commingled with milk being offered for sale.
 - b. External measuring rods must be cleaned and sanitized using a chlorine solution of one hundred parts per million or equivalent prior to use. Agitate farm bulk tank a minimum of five minutes for all tanks nine hundred gallons [3406.87 liters] or smaller and a minimum of ten minutes for all tanks larger than nine hundred gallons [3406.87 liters] before taking sample.
9. At least once a month, sanitize the pocket dial thermometer (immerse in sanitizer thirty seconds) and check milk temperature from it versus farm bulk tank thermometer. Record any discrepancy between the two on the farm inspection sheet. When the farm bulk tank thermometer deviates by more than plus or minus two degrees Fahrenheit [1.11 degrees Celsius] from the pocket dial thermometer, the pocket dial thermometer must be used during every milk pickup from the bulk tank in question. All milk in the farm bulk tank must be forty-five degrees Fahrenheit [7.22 degrees Celsius] or less to be eligible for pickup and transport off the farm.
10. Record the following on the sample container:
 - a. Date.
 - b. Time.
 - c. Temperature of milk.
 - d. Bulk hauler name or initial.
 - e. Producer name or number.

f. Any milk abnormalities (smell or sight).

The sampling container may not be preidentified before entering the farm milkroom.

11. The same item listed in subdivisions a through f of subsection 10 should be recorded on the temperature control sample with the notation "T.C." A "T.C." must be taken at the first stop of the day and the first producer on every other farm bulk route picked up that day. This sample is to be transported with the set of samples representing each truckload of milk.
12. Collect milk sample taking care to open sample container without contaminating interior of container or cap and sample only with agitator running. The agitator must have been running no less than five minutes for tanks with eight hundred gallons [3028.33 liters] or smaller and ten minutes for tanks over eight hundred gallons [3028.33 liters]. A sample must be taken from each tank used for raw milk storage on the farm at every pickup.

a. Metal dipper.

- (1) Rinse sampling device twice in milk before taking sample (sample through porthole).
- (2) Take sample four to six inches [10.16 to 15.24 centimeters] below level of milk.
- (3) Transfer to sample container. Do not pour into sample container over bulk tank porthole. Sample container is to be filled three-quarters full.
- (4) Close sample container. Replace porthole cover. Transport sample container to refrigerated sample case. The refrigerated sample case must contain sufficient room for a rack to maintain samples in an upright position. A water-ice mixture adequate to maintain milk samples at thirty-two to forty degrees Fahrenheit [0 to 4.4 degrees Celsius] must be utilized in the refrigerated sample case.
- (5) Rinse sample device in warm water and replace in carrying case.

b. Presterilize straws or pipettes.

- (1) With end of straw four to six inches [10.16 to 15.24 centimeters] below milk surface, close end of straw and transfer milk to sample container. Do not transfer directly over porthole. Fill sample

container three-quarters full and discard extra milk in straw (sample through porthole).

- (2) Close sample container. Replace porthole cover. Transport sample container to refrigerated sample case. Dispose of sample instrument.
13. With agitator running, open the bulk tank valve and turn on the farm bulk truck transfer pump. All covers should be closed during milk transfer except for farm bulk tanks which operate under vacuum. Vacuum tanks must have one cover slightly open to prevent tank collapse while transferring.
14. When the level of the milk drops below the agitator blade, shut off the agitator.
15. When the farm milk tank is empty, shut off the farm bulk truck pump, disconnect the milk transfer hose and cap if used. Place the sani-guide disk in a conspicuous place for the producer to observe or in a clean sanitary holder for transport to the plant.
16. Observe the bottom of the tank for sediment and abnormalities. Record any unusual observances on the weigh ticket and sample container.
17. Rinse the bulk tank with lukewarm water, with bulk tank valve open.
18. Clean up milkroom so it is left in a similar condition to the way it was prior to entering.

If the agitator is running when the farm sampler enters the milkroom, the sequence must be 1, 2, 3, 4, 5, 9, 10, 11, and 12. Then shut the agitator off and allow milk to become quiescent. Then finish by completing 6, 7, 8, 13, 14, 15, 16, 17, and 18. No sample may be taken through the farm bulk tank valve unless approved by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-10. Plant samplers.

1. Raw milk sampling procedures. Plant storage tanks or bulk milk tanks for storing raw milk without sampling cocks must be sampled using the same procedures described in sampling procedures for farm samplers in section 7-03.1-02-09, excluding the references for transferring milk.

2. For plant storage tanks with sampling cocks, all of the following procedures must be used:

- a. Rinse the area around the sample cock with warm water and clean if needed.
- b. Wash and dry hands.
- c. Sanitize sample cock by the use of one hundred parts per million of an approved chlorine sanitizer or equivalent. Use a minimum contact time of thirty seconds.
- d. Purge sample cock by discarding a volume of milk of sufficient quantity to remove any excess chlorine solution.
- e. Two sample containers must be labeled with the following information:
 - (1) Plant name.
 - (2) Date.
 - (3) Time.
 - (4) Temperature.
 - (5) Sampler name or initials.
 - (6) Tank or silo identification.

The sample container to be used for the temperature control must also have the "T.C." notation put on the sample container.

- f. Aseptically remove the top of the bag or cap cover of the sample container for the one marked "T.C." without touching the sample container to the sample cock. Fill the sample container three-quarters full, close, and place immediately in a refrigerated sample case with a water-ice mixture capable of keeping the sample temperature at thirty-two through forty degrees Fahrenheit [0 through 4.4 degrees Celsius].
- g. Sanitize an approved certified pocket dial thermometer by contact with an approved chlorine solution of one hundred parts per million or equivalent for a minimum of thirty seconds.
- h. Using the dial thermometer, or tank thermometer if certified within the last six months, obtain the temperature of the milk in the sample container. Write this temperature on both sample containers.

- i. Aseptically remove the top of the bag or cap of the remaining sample container and obtain a sample without touching the sample container to the sample cock. Fill the sample container three-quarters full. Close and place immediately in the refrigerated sample case.
- j. Rinse off all excess milk from the sample cock and storage tank or silo.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-11. Finished product sampling procedures. All finished product collected for regulatory use must be collected by the dairy commissioner or the commissioner's designated representatives. Samples must be collected in a random manner and the older code date must be selected before a more recent code date.

Finished product chosen for sampling must be stored in a refrigerated sample container capable of maintaining the samples at thirty-two to forty degrees Fahrenheit [0 to 4.4 degrees Celsius]. A temperature control sample must be selected for each area or cooler where finished milk product is being stored. The temperature control must be opened and a temperature obtained using a properly certified dial thermometer. The temperature control must be closed and sealed to prevent leakage during transport.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18

7-03.1-02-12. Adulterants.

1. Antibiotic screening.

- a. Raw milk. An approved screening test of each commingled farm truckload of milk must be conducted daily in lieu of individual producer testing. All positive screening tests must be immediately confirmed. A positive confirmatory test on the commingled sample will require confirmation testing for antibiotics of all individual producer samples making up the farm truck commingled load.

A reading of greater than twelve and eight-tenths millimeters but less than fifteen and eight-tenths millimeters on the Bacillus Stearothermophilus test of any individual producer's raw milk sample must be immediately reported to the dairy commissioner as below actionable level. A reading of sixteen milliliters or greater must be reported immediately to the dairy commissioner who

shall stop milk shipments until the milk offered for sale tests twelve and eight-tenths or below millimeters using the Bacillus Stearothermophilus tests or other test approved by the dairy commissioner.

- b. Finished product. All finished grade A milk products must be tested for antibiotics monthly. Raw milk contaminated with antibiotics may not be used in processing finished grade A products. All manufacturing grade finished milk products must be tested as determined by the dairy commissioner. These products include fluid and cultured products, butter, cheese, and other products so designated by the dairy commissioner.

A reading of twelve and eight-tenths millimeters or greater on the Bacillus Stearothermophilus must be immediately reported to the dairy commissioner who shall take appropriate action according to rule and statute. Plants using milk contaminated with antibiotics in manufacturing grade finished products shall notify the dairy commissioner. Antibiotic testing of finished dairy products by other governmental agencies must be accepted for meeting the requirements of this section upon approval of the dairy commissioner.

- 2. **Pesticides.** Milk containing any pesticides or chemical contamination over United States food and drug administration established standards for safe food may not be offered for sale.
- 3. **Added water.** Milk may not contain added water. Any milk testing over -0.540 degrees Horvet using the cryoscope thermistor test may not be offered for sale.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-18, 4-30-40

CHAPTER 7-03.1-03 CREAM PRODUCTION ON THE FARM

Section

7-03.1-03-01

General Requirements

7-03.1-03-02

Milk Facility Requirements

7-03.1-03-01. General requirements. Cream separated on the farm used for manufacturing milk products must be derived from milk meeting the requirements of the certification program established by the dairy department. Wet hand milking is prohibited. All farm separated cream

must be stored on the farm where produced for a period not exceeding seven days before being transported to a cream receiving station.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-21

7-03.1-03-02. Milk facility requirements. The milking facility must meet all of the following requirements:

1. Raw cream storage and milkroom:

- a. Walls and ceilings dusttight.
- b. Impervious floors.
- c. Only water or refrigerated air can be used to cool the cream and the storage containers may not be submerged.
- d. Adequate lighting, a minimum of ten foot-candles.
- e. Self-closing, tight-fitting outer door.
- f. Must be free from insects, rodents, and other vermin.

2. Milking area:

- a. Adequate lighting, a minimum of ten foot-candles.
- b. Dusttight ceilings, walls, and doors.

3. Water supply. The water supply must have been inspected and found to be in compliance with state water codes, or tested and found to be a safe water supply pursuant to the state department of health guidelines.

4. Premises and surroundings:

- a. Manure must be removed or stored so as to not create a fly problem and must be inaccessible to the milking herd.
- b. Cowyard must drain.
- c. Surroundings must be maintained so as to prevent rodent harborage.

5. Milking herd:

- a. Cattle must be kept clean and free of excess mud and manure.

- b. All cattle must be free of any disease which can be transmitted via the milk to humans. Fowl and swine may not be housed in proximity to the milking herd.

6. Equipment:

- a. Utensils, equipment, and all items used in handling milk must be free from rust.
- b. All new and replacement equipment must meet 3A standards as defined in North Dakota Century Code section 4-30-01 where standards are established.
- c. Tinned metal must be rust-free.
- d. Equipment must be cleaned and sanitized prior to each use.
- e. Equipment must be stored to prevent contamination after cleaning and sanitizing until used.

7. Temperature standards:

- a. Cream on the farm and during transport must be maintained at thirty-two to forty-five degrees Fahrenheit [0 to 7.22 degrees Celsius].
- b. Once in possession of the cream station or plant, cream must be stored within temperatures ranging of thirty-two to forty-five degrees Fahrenheit [0 to 7.22 degrees Celsius] and maintained at that temperature.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-21

**CHAPTER 7-03.1-04
SEDIMENT TESTING**

Section

7-03.1-04-01 Sediment Testing Program
7-03.1-04-02 Classifications

7-03.1-04-01. Sediment testing program.

- 1. At least once each month one can of cream from each producer, seller, or shipper of farm separated raw cream must be selected at random and tested for sediment content by using the "off-the-bottom" or the "mixed can" method. The results of this sampling must be sent to the dairy department.

2. If a producer's cream is classified number one or number two, on the basis of the regular monthly sediment test, the cream must be accepted, and no further testing is necessary until the next routine test period. If the cream is classified number three because of sediment content, the producer, seller, or shipper must be put on probational status and the next three successive deliveries must be tested. If these three successive deliveries are classified number one or number two, the producer, seller, or shipper must be taken off the probational status and the cream thereafter tested by the regular routine testing program. If the cream is still classified as number three on these deliveries, each delivery thereafter must be tested before acceptance and cream in which the sediment content is in excess of number two must be rejected. This continuous testing must be continued until three successive deliveries are classified as number one or number two. Thereafter, the producer, seller, or shipper must be removed from the probational status and tested by the regular routine sediment testing program. If cream is classified as "reject," the cream must be returned to the seller or colored with a harmless vegetable dye, or both, and the routine prescribed in this subsection for testing probational cream must be followed.

3. When cream from a producer falls below grade number two, the cream buyer will notify the state dairy commissioner. A special sanitary inspection will be conducted of the producer's facility. If a producer's facility does not meet the standards for the production of cream, the dairy commissioner may order their cream suspended from the market until unsatisfactory conditions have been corrected.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-23

7-03.1-04-02. Classifications. For the purpose of quality control and establishing a rejection level of cream to the producer, seller, or shipper, the following classification of cream for sediment is applicable:

Classification	Bacteria Count per ml.	Sediment (Off-the-bottom method)	Sediment (Mixed-can method)
Number 1 (Acceptable)	Less than 500,000	Not to exceed 0.50 milligrams	Not to exceed 0.20 milligrams
Number 2	Less than	Not to exceed	Not to exceed

(Acceptable)	1,000,000	1.00 milligrams	0.30 milligrams
Number 3 (Probational)	Greater than 1,000,000	Not to exceed 2.50 milligrams	Not to exceed 1.00 milligrams
Number 4 (Reject)		Over 2.50 milligrams	Over 1.00 milligrams

(Cream must also be classified reject when two consecutive tests result in the cream being classified number 3)

1. Accurate plant records listing the results of quality tests made on raw cream must be maintained on cream from each producer, seller, or shipper. Each producer, seller, or shipper shipping probational or rejected cream, must be informed immediately of results of such quality tests. Producers, sellers, or shippers shipping number one and number two cream should receive such information at the time of regular remittances. Such records must be available for examination by the inspector and kept on file for at least one year. Alternately, when a processor has in operation an acceptable quality program, at the producer level, which is approved by the dairy department as being effective in obtaining results comparable to or higher than the quality program as outlined in section 7-03.1-04-01 for cream, then such a program may be accepted in lieu of the program outlined in section 7-03.1-04-01.
2. All containers used for sale of raw cream must be identified in order that they may be distinguished from containers with similar appearance. A log identifying the producer container, and sediment testing and butterfat testing results, must be maintained by the cream station for the period of one year.
3. Sediment testing to determine classification of cream must be conducted by individuals licensed by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-23

CHAPTER 7-03.1-05 CREAM STATION REQUIREMENTS

Section	
7-03.1-05-01	Facilities
7-03.1-05-02	Vector Control
7-03.1-05-03	Cream Container Requirements

7-03.1-05-01. Facilities. Cream stations shall provide all of the following facilities:

1. Laboratory area - adequate size and facilities to conduct butterfat and sediment testing.
2. Cooling facilities - used for the storage of cream samples and for resale or processing shall maintain a storage temperature between thirty-two to forty-five degrees Fahrenheit [0 to 7.22 degrees Celsius].
3. External loading facilities, if present, must have insect-tight and dusttight, self-closing outer doors.
4. Floors:
 - a. Cream stations with processing facilities must have concrete or tile floors in the cream receiving area.
 - b. Cream stations without processing facilities must have well maintained wood, linoleum, or other flooring material acceptable to the dairy commissioner.
5. Hand wash sinks and double vat sinks or can steamers.
6. Adequate supply of hot and cold running water.
7. Storage facilities for raw cream must be 3A approved standards, as defined in North Dakota Century Code section 4-30-01, and must be constructed of stainless steel or other material as accepted by the dairy department.
8. The cream receiving area must have trapped drains leading to an approved sewage disposal system.
9. A separate room for receiving and washing raw cream containers (i.e., cans) are required if processing of milk products is conducted in the same facility.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-25

7-03.1-05-02. Vector control. Insecticides and rodenticides used in fly and rodent control must be utilized according to container label. All insecticides and rodenticides must be approved for use by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-25

7-03.1-05-03. Cream container requirements. Cans, including lids, may not show open seams, cracks, rust, milkstone, or other unsanitary conditions. Patrons must be informed of unsatisfactory cans or containers. Cream offered for sale in unsanitary containers must be dyed with a harmless vegetable color and returned to the patron. No cream station cans may show signs of rust, open seams, milkstone, or be in an unsanitary condition.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-25

CHAPTER 7-03.1-06 MANUFACTURING FARM INSPECTION REPORTS

Section	
7-03.1-06-01	Health of Herd
7-03.1-06-02	Milk Offered for Sale Shall be Wholesome and Unadulterated
7-03.1-06-03	Water Supply
7-03.1-06-04	Milk Truck Approach
7-03.1-06-05	Sewage Disposal
7-03.1-06-06	Milkhouse or Milkroom
7-03.1-06-07	Utensils and Equipment
7-03.1-06-08	Bulk Milk
7-03.1-06-09	Milking Area
7-03.1-06-10	Yard, Loafing Area, or Premises
7-03.1-06-11	Milking Procedures
7-03.1-06-12	Inspection Procedures and Enforcement - Farm Inspection

7-03.1-06-01. Health of herd. The milk offered for sale must be obtained from healthy cows.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-02. Milk offered for sale must be wholesome and unadulterated.

1. Milk must be tested monthly by either the direct microscopic count or the standard plate count to determine bacteria compliance. Milk must be classified for bacterial estimates based on either of these tests:

- | | |
|-------|--|
| No. 1 | Not over five hundred thousand per milliliter. |
| No. 2 | Not over one million per milliliter. |

2. Milk must be tested monthly to determine compliance with the somatic cell count. Determination of compliance may be by either of the following methods: the direct microscopic somatic cell count - single strip, electronic somatic cell counting, optical somatic cell counting, membrane filter deoxyribonucleic acid somatic cell counting, or screening tests of the Wisconsin Mastitis Test. The milk must test below one million somatic cells per milliliter of milk by the direct microscopic somatic cell count or below nineteen on the Wisconsin Mastitis Test. If the Wisconsin Mastitis Test is used and the test exceeds eighteen, then a confirmatory direct microscopic somatic cell count must be run to determine compliance.
3. A producer's raw milk must be classified as undergrade when:
 - a. Monthly bacteria counts by the direct microscopic cell count or standard plate count exceed one million;
 - b. Two out of the last four monthly somatic cell counts exceed one million;
 - c. The sediment content exceeds one and five-tenths or equivalent by the mixed sample method;
 - d. The last two dairy facility inspections scored below eighty-five; or
 - e. The same inspection item has been debited consecutively on the last three dairy facility inspections.

Milk classified as undergrade because of bacterial quality on two successive monthly tests, must be rejected from the market.

Milk classified as undergrade because of somatic cell counts will result in a warning letter sent to the producer. No sooner than three days nor later than twenty-one days after the first warning letter, another sample must be taken and, if this test exceeds one million, the dairy commissioner shall reject the milk from the market.

Milk classified as undergrade because of sediment content must be resampled and tested between three and twenty-one days following notice of violation and if found to exceed one and fifty hundredths milligrams by the mixed sampling method or equivalent must be rejected from the market.

Milk classified as undergrade because of inspection score or three consecutive violations of an inspection item, if not corrected within thirty days from being classified undergrade, will result in certification being suspended.

Reinstatement of certification status cannot be accomplished until conditions leading to the undergrade status have been corrected by evidence of either test results or a satisfactory inspection of the facility, as determined by the dairy commissioner.

4. Wholesomeness. Milk offered for sale must be tested monthly to determine sediment content. The sediment standard is:

No. 1 Not to exceed fifty-hundredths milligrams or equivalent

No. 2 Not to exceed one and fifty-hundredths milligrams or equivalent

Note: All sediment tests must be by the mixed sample method, unless otherwise approved by the dairy commissioner.

5. Volume requirement. The volume of milk in the bulk tank after the first milking must reach the agitator to such a level that adequate agitation of the milk is possible. Failure to produce adequate volumes on the first milking will result in suspension of a producer's certification to sell raw milk.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27, 4-30-31

7-03.1-06-03. Water supply.

1. The dairy facility water supply must be properly located, protected, and operated and must be of ample supply and safe for the cleaning of utensils and equipment. Rural farm water supplies approved by the state department of health are acceptable. Wells constructed in compliance with state board of water well contractors and tested every three years by an approved laboratory and found to be satisfactory are acceptable. Other water supplies approved by the dairy commissioner and tested annually and found to be satisfactory are acceptable. All water sources must be tested following repairs or other disruptions to the water system and must be found satisfactory. All new water supplies to the dairy facilities must be in compliance with either the state department of health requirements for rural water or the state board of water well contractors requirements for well construction.
2. A separate handwashing facility, including soap, individual sanitary towels, and hot and cold water under pressure with a mixing faucet, hand sink, or washbasin must be provided.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-04. Milk truck approach. The milk truck approach to the dairy facility must be such as to prevent excess mud and to allow easy access to the milkroom. Farm animals may not have free access to the truck approach area.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-05. Sewage disposal. House, milkhouse, or milkroom and toilet wastes must be disposed of in a manner that will not pollute the soil surface, contaminate any water supply, or be exposed to insects.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-06. Milkhouse or milkroom.

1. A milkhouse or milkroom conveniently located and properly constructed, lighted, and ventilated must be provided for handling and cooling milk and for washing, handling, and storing the utensils and equipment. Light fixtures over a bulk tank must be constructed of shatterproof materials.
2. The floor of the building must be of concrete or other impervious material and graded to provide proper drainage. The walls and ceilings must be constructed of smooth, easily cleaned material, and must be dusttight.
3. All outside doors must be self-closing, unless they are provided with tight-fitting screen doors that open outward or unless other effective means are provided to prevent the entrance of flies. If a part of the barn or other building, the milkhouse or milkroom must be partitioned, screened, and sealed to prevent the entrance of dust, flies, or rodents. Solid doors between the milkroom and milking area are required to be tight-fitting and self-closing.
4. The milkhouse or milkroom must be equipped with a wash and a rinse vat constructed of material approved by the dairy commissioner, a utensil rack, and milk cooling facilities, and must have an adequate supply of hot and cold water under pressure for cleaning of the milking equipment.

5. Other products may not be handled in the milkroom which would be likely to contaminate milk, or otherwise create a public health hazard.
6. The milkhouse or milkroom and appurtenances must be kept clean and free of trash, animals, and fowl.
7. Single-service articles must be properly stored and may not be reused.
8. Only pesticides approved for uses in the milkroom with an environmental protection agency number may be stored in the milkroom and when used must be used in accordance with label instructions so as to prevent contamination of the milk. Antibiotics and other medicinals may be stored in the milkroom if stored in a safe manner, to not contaminate the milk supply or milk contact equipment.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-07. Utensils and equipment. Utensils and equipment used in the milking and milk handling operations must be in good repair, clean, and properly stored. Cleaning equipment must be in satisfactory condition and properly stored. All milk contact surfaces must be free of milk and other residue buildup and must be maintained in a sanitary condition. Milk contact surfaces must be washed, rinsed, drained, and stored in a sanitary manner after each use and must be sanitized immediately prior to each use. All utensils and equipment must comply with applicable 3A sanitary standards as defined in North Dakota Century Code section 4-30-01. Approved dairy cleaners, sanitizers, and brushes must be available in the milkroom or adjacent approved storage area.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-08. Bulk milk.

1. A bulk milk tank that meets 3A sanitary standards as defined in North Dakota Century Code section 4-30-01 for construction must be provided. Milk may not be stored in the milkroom in unapproved containers or offered for sale in any unapproved container. The tank will be equipped with an approved milk measuring device, and a conversion table to determine pounds [kilograms] will be in the milkroom.
2. The bulk tank must be cleaned after each milk pickup and sanitized prior to refilling the tank. New tanks must be equipped with a tight-fitting, 3A sanitary standards, as

defined in North Dakota Century Code section 4-30-01, approved valve designed for use on a bulk tank. Existing tanks must be equipped with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, approved valves or other valves acceptable to the dairy commissioner. Valves not designed for cleaning-in-place cleaning must be taken apart and hand-cleaned and sanitized between milk pickup and refilling.

3. Milk in farm bulk tanks must be cooled to forty degrees Fahrenheit [4.4 degrees Celsius] or lower within two hours after milking and maintained at forty-five degrees Fahrenheit [7.22 degrees Celsius] or lower until transferred to the transport tank, and blended milk may not exceed fifty degrees Fahrenheit [10 degrees Celsius]. All bulk tanks will be equipped with a thermometer accurate to within plus or minus two degrees Fahrenheit [1.11 degrees Celsius]. Milk may not be held longer than ninety-six hours on the farm from the first milking to pickup, except during storm-related conditions. Any time milk is removed from the bulk tank, the tank must be completely emptied, washed, and sanitized prior to the next milking. Milk offered for sale must be removed from the tank only through the tank milk valve.
4. The farm bulk tank must be properly located in the milkhouse or milkroom for access to all areas for cleaning and servicing. It may not be located over a floor drain or under a ventilator.
5. A platform or slab constructed of concrete or other impervious material must be provided outside the milkhouse, properly centered under a suitable port opening in the wall for transferring milk from the bulk tank to the milk truck. On new construction, a minimum of six foot by six foot [1.83 meter by 1.83 meter] slab is required. The port opening must be closed when not in use.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-09. Milking area.

1. A milking barn or milking parlor of adequate size and arrangements must be provided for sanitary milking operations.
2. No swine or fowl are permitted in any part of the milking area.
3. The milking area must be well lighted and ventilated, and the floors and gutters in the milking area must be constructed of concrete or other impervious material, and must be in good

repair. The milking areas must be protected from particles from areas outside the milking facility. The walls and ceilings must be in good repair. The facility must be kept clean. The manure must be removed daily and stored to prevent access to the cows.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-10. Yard, loafing area, or premises. The facility must be kept clean. The manure must be removed daily and stored to prevent access to cows. The yard or loafing area must be of ample size to prevent overcrowding, must be drained to prevent forming of standing water pools, and must be kept clean. Manure must be spread daily or stored in an approved manner. Stacked or piled manure and manure packs in housing facilities must be spread prior to fly season each year (approximately June 15).

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-11. Milking procedures.

1. All milking cows must be kept clean. The udders and teats must be washed and wiped immediately before milking with a clean, damp cloth or paper towel moistened with a sanitizing solution and wiped dry. Other sanitary udder wash methods may be approved by the dairy commissioner.
2. The milker's outer clothing must be clean. The milker's hands must be clean and dry. No person with an infected cut or open sores on their hands or arms may milk cows or handle milk or milk containers, utensils, or equipment.
3. Milk from cows known to be infected with mastitis, residues of antibiotics or other drugs, milk containing pesticides or other chemical residues in excess of the established state or federal limits, or milk from cows during the first ninety-six hours after freshening (colostrum) must be milked last or with separate equipment and must be excluded from the market.
4. Milk stools, surcingles, and antikickers must be kept clean and properly stored.
5. Dusty operations may not be conducted immediately before or during milking. Strong flavored feeds are to be fed after milking.

6. Concentrates and feed, if stored in the building, must be kept in a tightly covered box or bin.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27

7-03.1-06-12. Inspection procedures and enforcement - Farm inspection.

1. Farms scoring ninety-two or higher on farm inspections, with all violations on the preceding inspection corrected, must be inspected at a frequency of every four to six months.
2. Farms scoring between ninety-one and eighty-five, with all violations on the preceding inspections corrected, must be inspected at a frequency of every sixty to one hundred twenty days.
3. Farms scoring below eighty-five, or farms with two successive violations, must be reinspected at a frequency of every fourteen to forty-five days.
4. Items for which the dairy commissioner has established a compliance deadline are exempted until the deadline has expired.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-27, 4-30-28

**CHAPTER 7-03.1-07
CERTIFICATION PROCEDURES FOR ALL NORTH DAKOTA
DAIRY FACILITIES**

Section	
7-03.1-07-01	General Requirements for the Certification of New Milking Facilities
7-03.1-07-02	Special Requirements for the Certification of New Milking Facilities
7-03.1-07-03	Rejection of Certification and Appeal
7-03.1-07-04	Temporary Facilities' Certification for the Sale of Raw Milk

7-03.1-07-01. General requirements for the certification of new milking facilities.

1. All dairy farms wishing to sell milk shall make application for farm certification pursuant to North Dakota Century Code

section 4-30-28. No dairy farm may sell milk or cream without state certification.

2. Application must be made by letter to the office of the state dairy commissioner, state capitol, Bismarck, North Dakota, at least twelve days before inspection of facilities and premises by the state dairy department.
3. A set of plans containing information on the dairy farm, milking facility, and milking equipment must be submitted to the dairy commissioner for new dairy facilities or major changes in existing facilities. This information must be provided by the dairy producer and accepted by the dairy commissioner prior to the start of any improvements.
4. A facility inspection must be conducted and a water sample taken as a requirement for certification. Satisfactory results from both these items will result in the posting of an inspection sheet which represents certification of that facility to sell milk in the state of North Dakota.
5. The inspection sheet must be prominently posted on the premises and is prima facie evidence in all proceedings by and before the dairy commissioner for compliance of premises and facilities with all the provisions of North Dakota Century Code chapter 4-30.
6. Dairy farm facilities will be certified according to approved uses as:
 - a. Grade A - A production unit that is certified by the dairy department to meet state production practices as required by North Dakota Century Code section 4-30-36.
 - b. Manufacturing grade - A production unit that is certified by the dairy department to meet state production requirements as required by North Dakota Century Code section 4-30-27.
 - c. Cream grade - A production unit that is certified by the dairy department to meet state production requirements as required by North Dakota Century Code section 4-30-21.
7. Certification is continuous unless suspended or revoked and is not transferable.
8. Any dairy facility temporarily not in use during a normally scheduled inspection is required to be recertified prior to the start of raw milk or cream sale.
9. All certified producers will be assigned a producer number by the dairy commissioner. This number must be used by the

producer, bulk hauler, and plant when communicating with the dairy department.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-28

7-03.1-07-02. Special requirements for the certification of new milking facilities.

1. Grade A milk farm.

a. The water supply must be tested by an approved state water testing laboratory and found to contain less than one coliform per milliliter of water by the membrane filter method, or less than two and two-tenths coliforms per milliliter of water if tested by the most probable number method; a source from which the supply has been approved for municipal or rural water supply by the state department of health; a well constructed in compliance with North Dakota board of water well contractors requirements for water wells for domestic use; or for existing wells that are of approved construction, a pit that meets the following minimum requirements is acceptable:

- (1) Walls must be watertight and extend above ground surface a minimum of six inches [15.24 centimeters].
- (2) A concrete floor sloping to an externally discharging drain or sump equipped with sump discharging to the surface is required.
- (3) All pumps located in the pit must be mounted a minimum of twelve inches [30.48 centimeters] above the floor of the pit.
- (4) A watertight overlapping cover is required on the pit.

b. A farm score of ninety or better by a dairy department inspector at the time the certification inspection is conducted is required and all the following must be met:

- (1) All construction requirements have been found in compliance or an acceptable date agreed to for compliance.
- (2) All milk contact equipment and utensils must meet 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, construction or cooling requirements, provided 3A sanitary standards, as

defined in North Dakota Century Code section 4-30-01, have been adopted.

- (3) The farm bulk tank must be empty at the time of certification.

2. **Manufacturing grade milk farm.**

- a. Water supply has been tested and found safe by a state-approved water testing laboratory.
- b. The farm has obtained a minimum score of ninety on its certification inspection and all the following are met:
 - (1) All construction requirements are in compliance or a satisfactory compliance date has been agreed to.
 - (2) All milk contact and cooling equipment meets the requirements for manufacturing milk production.

3. **Cream grade farms.**

- a. The water supply has been inspected and found in compliance with state water codes, or tested and found to be a safe water supply pursuant to the state department of health guidelines.
- b. The farm has been inspected and found to be in adequate compliance to assure the production, handling, and storage of a safe and wholesome cream supply.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-28

7-03.1-07-03. **Rejection of certification and appeal.**

1. Should the inspection determine that deficiencies exist which prevent certification of the farm, the farm may not be certified.
2. The producer shall correct all deficiencies prior to requesting a reinspection.
3. A dairy producer denied certification may appeal that decision to the dairy commissioner within thirty days of the denial, by requesting, in writing, a hearing. Upon receipt of the request for a hearing, the dairy commissioner shall convene a hearing as soon as possible, but not later than fifteen days after receiving the request. All interested parties must be given notice to attend the hearing. Notice may be oral notice if time does not allow for written notice. The hearing must

otherwise be in accordance with North Dakota Century Code chapter 28-32. The dairy commissioner shall issue a written decision including findings and conclusions in regard to certification, if certification is denied.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-28

7-03.1-07-04. Temporary facilities' certification for the sale of raw milk.

1. Application must be made to the dairy commissioner for certification of temporary facilities set up for dairy shows, fairs, etc.
2. These must comply with all construction requirements in North Dakota Century Code chapter 4-30 for farm facilities offering raw milk for sale. Under no circumstances may lactating dairy animals be housed with fowl, swine, or other potential carriers of milk-borne illness.
3. An onsite facility inspection must be conducted prior to the sale of any milk and, if acceptable, the temporary permit must consist of the posted inspection sheet. The permit length must be determined by the dairy commissioner.
4. All milk offered for sale from facilities with temporary permits must be screened for inhibitory substances by use of the Delvo P or other tests accepted by the dairy commissioner. The person administering the test must be a licensed tester.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-28

**CHAPTER 7-03.1-08
TRANSFER PROCEDURES FOR ALL DAIRY PRODUCTS**

Section
7-03.1-08-01 Transfer Procedures

7-03.1-08-01. Transfer procedures.

1. Dairy producers must meet minimum quality and inspection standards to be eligible to sell their milk. To ensure that this regulation is effective, all current dairy producers who want to transfer between plants shall make application to the

dairy commissioner for authority to transfer. The application must be made on forms provided by the dairy commissioner.

2. Upon receipt of an application, the dairy commissioner shall examine the inspection and milk quality records of that producer. If the producer's records indicate that the producer meets minimum milk quality standards for the respective grade of milk being sold and the producer is under no suspension or suspension warning, the dairy commissioner shall immediately approve the transfer application and mail a copy to the dairy producer and plants involved. Should the producer's records leave doubt about whether minimum standards are met, the dairy commissioner shall immediately order a sample of milk be taken or an inspection of the dairy facility, or both, to determine compliance. If said inspection (minimum score of eighty-five for manufacturing grade and ninety for grade A required) and milk quality tests conclude that the producer meets minimum standards, the dairy commissioner shall immediately approve the transfer and notify the interested parties.
3. In all cases, the dairy commissioner shall approve or disapprove the application to transfer in writing, within seven days. The transfer is effective, if approved, no sooner than fourteen days after receipt of the application by the dairy commissioner.
4. No transfer may be approved while a producer is under a warning of intent to suspend for failure to meet any minimum quality standard for raw milk offered for sale.
5. Upon written request of the dairy producer, within thirty days of the denial of a transfer request, the dairy commissioner shall convene a hearing, within fifteen days of receiving the written request, to determine the circumstances of the disputed transfer and whether the denial is proper. The hearing must otherwise be in accordance with North Dakota Century Code chapter 28-32. The dairy commissioner shall issue written findings and conclusions from the hearing if transfer is denied.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-23

**CHAPTER 7-03.1-09
MILK AND MILK PRODUCTS STANDARDS OF IDENTITY
AND QUALITY**

Section

7-03.1-09-01

Chemical, Physical, Bacteriological, and

7-03.1-09-02 Temperature Standards
 Enforcement Procedures

7-03.1-09-01. Chemical, physical, bacteriological, and temperature standards. The following chemical, physical, bacteriological, and temperature standards apply to milk and milk products standards of identity and quality:

1. Commingled Grade A raw milk for pasteurization
 - Temperature Milk must be received and maintained not to exceed fifty degrees Fahrenheit [10 degrees Celsius] while in storage.
 - Bacterial limit Not to exceed three hundred thousand per milliliter prior to pasteurization.
 - Antibiotics Not to equal or exceed sixteen millimeter zone with the Bacillus Sterothermophilus disc assay method.

2. Grade A pasteurized milk and milk products
 - Temperature Cooled to forty-five degrees Fahrenheit [7 degrees Celsius] or less and maintained thereat.
 - Bacterial limit Twenty thousand per milliliter.
 - Coliform Not to exceed ten per milliliter, provided that, in the case of bulk milk transport tank shipments, it shall not exceed one hundred per milliliter.
 - Phosphatase Less than one microgram per milliliter by the Scharer Rapid Method or equivalent.
 - Antibiotics No zone greater than or equal to sixteen millimeters with the Bacillus Sterothermophilus disc assay method.

3. Grade A pasteurized condensed milk
- Temperature Cooled to forty-five degrees Fahrenheit [7 degrees Celsius] or less and maintained at that level unless drying is commenced immediately after condensing.
- Bacterial limit Not to exceed thirty thousand per gram.
- Coliform limit Not to exceed ten per gram.
- Antibiotics No zone greater than or equal to sixteen millimeters with the Bacillus Sterothermophilus disc assay method.
- Phosphatase Less than one microgram per milliliter by the Scharer Rapid Method or equivalent.
4. Grade A nonfat dry milk
- Not more than:
- Butterfat One and twenty-five-hundredths percent.
- Moisture Four percent.
- Titratable acidity Fifteen-hundredths percent.
- Solubility index One and twenty-five-hundredths milliliters.
- Bacterial estimate Thirty thousand per gram.
- Coliform Ten per gram.
- Scorched particles disc B Fifteen per gram.
- Antibiotics No zone greater than or equal to sixteen millimeters with the Bacillus Sterothermophilus disc assay method.
5. Grade A whey for condensing
- Temperature Maintained at a temperature of forty-five degrees Fahrenheit [7 degrees Celsius] or less, or one hundred forty-five degrees Fahrenheit [63 degrees Celsius] or greater except for acid-type whey with a titratable acidity

		of forty-hundredths percent or above or a pH of four and sixty-hundredths or below.
	Antibiotics	No zone greater than or equal to sixteen millimeters with the Bacillus Sterothermophilus disc assay method.
6. Grade A pasteurized condensed whey	Temperature	Cooled to forty-five degrees Fahrenheit [7 degrees Celsius] or less during crystallization, within eighteen hours of condensing.
	Bacterial limit	Not to exceed thirty thousand per gram.
	Coliform limit	Not to exceed ten per gram.
	Antibiotics	No zone greater than or equal to sixteen millimeters with the Bacillus Sterothermophilus disc assay method.
	Phosphatase	Less than one microgram per milliliter by the Scharer Rapid Method or equivalent.
7. Grade A dry whey	Bacterial limit	Not to exceed thirty thousand per gram.
	Coliform limit	Not to exceed ten per gram.
	Antibiotics	No zone greater than or equal to sixteen millimeters with the Bacillus Sterothermophilus disc assay method.
8. US Extra grade dry buttermilk	Bacterial estimate	Not more than fifty thousand per gram.
	Butterfat	Not less than four and fifty-hundredths percent.

	Moisture	Not more than four percent.
	Scorched particle content	Not more than fifteen milligrams for the spray process and twenty-two and fifty-hundredths milligrams for the roller process.
	Solubility index . . .	Not more than one and twenty-five hundredths milliliters for the spray process and fifteen milliliters for the roller process.
	Titratable acidity . .	Not less than ten-hundredths percent; not more than eighteen-hundredths percent.
9. US Standard grade dry buttermilk	Bacterial estimate . .	Not more than two hundred thousand per gram.
	Butterfat	Not less than four and fifty-hundredths percent.
	Moisture	Not more than five percent.
	Scorched particle content	Not more than twenty-two and fifty-hundredths milligrams for the spray process and thirty-two and fifty-hundredths milligrams for the roller process.
	Solubility index . . .	Not more than two milliliters for the spray process and fifteen milliliters for the roller process.
	Titratable acidity . .	Not less than ten-hundredths percent; not more than twenty-hundredths percent.

10. US Extra grade whole milk	Bacterial estimate	Not more than fifty thousand per gram standard plate count.
	Coliform estimate	Not more than ten per gram.
	Milkfat	Not less than twenty-six percent, but not greater than forty percent.
	Moisture	Not more than four and fifty-hundredths percent (as determined by weight of moisture on a milk solids not fat basis).
	Scorched particle content	Not more than fifteen milligrams for spray process and twenty-two and fifty-hundredths milligrams for roller process.
	Solubility index	Not more than one milliliter for spray process, and fifteen milliliters for roller process.
11. US Standard grade dry whole milk	Bacterial estimate	Not more than one hundred thousand per gram standard plate.
	Coliform estimate	Not more than ten per gram.
	Milkfat	Not less than twenty-six percent, but not greater than forty percent.
	Moisture	Not more than five percent (as determined by weight of moisture on a milk solids not fat basis).
	Scorched particle content	Not more than twenty-two and fifty-hundredths milligrams for spray process and thirty-two and fifty-hundredths milligrams for roller process.

	Solubility index . . .	Not more than one and fifty-hundredths millimeters for spray process, and fifteen milliliters for roller process.
12. US Extra grade fat dry milk - (Roller Process)	Bacterial estimate . .	Not more than fifty thousand per gram standard plate count.
	Butterfat	Not more than one and twenty-five-hundredths percent.
	Moisture	Not more than four percent.
	Scorched particle content	Not more than twenty-two and fifty-hundredths milligrams.
	Solubility index . . .	Not more than fifteen milliliters.
	Titratable acidity . .	Not more than fifteen-hundredths percent.
13. US Standard grade nonfat dry milk (Roller Process)	Bacterial estimate . .	Not more than one hundred thousand per gram standard plate count.
	Butterfat	Not more than one and fifty-hundredths percent.
	Moisture	Not more than five percent.
	Scorched particle content	Not more than thirty-two and fifty-hundredths milligrams.
	Solubility index . . .	Not more than fifteen milliliters.
	Titratable acidity . .	Not more than seventeen-hundredths percent.
14. US Extra grade instant nonfat dry milk	Bacterial estimate . .	Not more than thirty thousand per gram standard plate count.

	Coliform count	Not more than ten per gram.
	Milkfat	Not more than one and twenty-five-hundredths percent.
	Moisture	Not more than four and fifty-hundredths percent.
	Scorched particle content	Not more than fifteen milligrams.
	Solubility index . . .	Not more than one milliliter.
	Titratable acidity . .	Not more than fifteen-hundredths percent.
	Dispersibility	Not less than eighty-five percent.
15. US Extra grade fat dry milk (Spray Process)	Bacterial estimate . .	Not more than fifty thousand per gram standard plate count.
	Butterfat	Not more than one and twenty-five-hundredths percent.
	Moisture	Not more than four percent.
	Scorched particle content	Not more than fifteen milligrams.
	Solubility index . . .	Not more than one and twenty-hundredths milliliters except that product classified as US High Heat may have more than two milliliters.
	Titratable acidity . .	Not more than fifteen-hundredths percent.
16. US Standard grade nonfat dry milk (Spray Process)	Bacterial estimate . .	Not more than one hundred thousand per gram standard plate count.
	Butterfat	Not more than one and fifty-hundredths percent.

	Moisture	Not more than five percent.
	Scorched particle content	Not more than twenty-two and fifty-hundredths milligrams.
	Solubility index . . .	Not more than two milliliters except that product classified as US High Heat may have not more than two and fifty- hundredths milliliters.
	Titratable acidity . .	Not more than seventeen- hundredths percent.
17. US Extra grade dry whey	Bacterial estimate . .	Not more than fifty thousand per gram standard plate count.
	Coliform	Not more than ten per gram.
	Milkfat	Not more than one and fifty-hundredths percent.
	Moisture	Not more than five percent.

Requests for standards of identity of products not previously defined, must be made in writing to the dairy commissioner who is responsible for developing the standards of identity for the product in question.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-35, 4-30-36

7-03.1-09-02. Enforcement procedures.

1. Whenever three of the last five consecutive bacteria, somatic cell, or coliform counts exceed the standards of section 7-03.1-09-01, immediate suspension of the permit for the plant processing the product in violation will occur.
2. Whenever any phosphatase test is positive, an investigation to determine the cause must be made by the dairy commissioner and the product in question may not be offered for sale until the investigation determines the cause of the problem.
3. Whenever any antibiotic or pesticide test results in a level exceeding the limits established in section 7-03.1-09-01, the product in question must be removed from the market and an

freezer and delivering it directly to the ultimate consumer are exempt from licensing.

3. All frozen dessert processors must be inspected once each six months at the direction of the dairy commissioner.
4. All new equipment utilized by frozen dessert processors must comply with 3A sanitary standards as defined in North Dakota Century Code section 4-30-01. Modifications of plant processes for the manufacture of frozen desserts must be submitted to the dairy commissioner for review prior to installation or construction.
5. All ingredients, including ice cream mix, must originate from plants approved by the United States department of agriculture, the food and drug administration, or state inspection.
6. Sanitary requirements, at a minimum, shall comply with United States department of agriculture general specifications for approved dairy plants and standards for grades of dairy products.
7. Samples must be collected by the dairy commissioner or the commissioner's appointed representative from each frozen dessert establishment or distributor, in the case of frozen desserts that originate outside the jurisdiction of the regulatory authority, at a frequency of four samples within a six-month period.
8. Samples must be handled in accordance with requirements of the latest edition of "Standard Methods for the Examination of Dairy Products" and those conditions stated in North Dakota Century Code section 4-30-18. Samples must be tested at laboratories approved by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-33, 4-30-35, 4-30-36

7-03.1-11-02. Microbiological requirements for ice cream, ice milk, and ice cream mix. The microbiological requirements for ice cream, ice milk, and ice cream mix are:

1. **Frozen desserts, including artificially sweetened.**
 - a. **Ingredients - Raw milk and dairy products.**
 - (1) **Milk - Maximum plant delivery temperature -
forty-five degrees Fahrenheit
[7.22 degrees Celsius]
- Raw for pasteurization five hundred**

thousand per milliliter standard
plate count

- (2) Cream - Maximum plant delivery temperature -
forty-five degrees Fahrenheit
[7.22 degrees Celsius]
- Raw for pasteurization eight hundred
thousand per milliliter standard
plate count

b. Pasteurized dairy products.

- (1) Phosphatase - The phenol value may be no greater than the minimum specified for the particular product as determined by the phosphatase test of the latest edition of Standard Methods, or other tests approved by the dairy commissioner.

- (2) Coliform requirements.

- (a) Frozen dessert (plain) - Coliform determination not more than ten milliliters. Storage temperature not more than forty-five degrees Fahrenheit [7.22 degrees Celsius]. Bacteria count not more than fifty thousand per milliliter.

- (b) Frozen dessert (flavored) - Meets all the requirements of subdivisions a and b. Coliform determination, however, may not be more than twenty per milliliter.

c. Dry dairy ingredients. United States extra grade or better, unless otherwise approved by the dairy commissioner.

2. **Butter.** Proteolytic count not more than one hundred per gram. Yeast and mold not more than twenty per gram. Coliform count not more than ten per gram.
3. **Whipped butter.** Proteolytic count not more than one hundred per gram. Yeast and mold not more than twenty per gram. Coliform count not more than ten per gram. Eterococci not more than ten per gram.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-33, 4-30-35, 4-30-36

7-03.1-11-03. Resampling. When a sample exceeds the microbiological requirements, the licensed operator must be notified in writing. An additional sample must be taken in not less than three days

nor more than twenty-one days from the notification. When two samples out of four consecutive samples are not in compliance, a warning must be sent. An inspection must be made at this time to determine sanitary conditions. When three out of five consecutive samples are not in compliance, sale of the product must be stopped until the test results are in compliance.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-33, 4-30-35, 4-30-36

**CHAPTER 7-03.1-12
SANITATION REQUIREMENTS FOR FARMS PRODUCING
GRADE A RAW MILK FOR PASTEURIZATION, ULTRAPASTEURIZATION,
OR ASEPTIC PROCESSING**

Section	
7-03.1-12-01	Abnormal Milk
7-03.1-12-02	Milking and Cow Area
7-03.1-12-03	Milkhouse or Milkroom
7-03.1-12-04	Toilet
7-03.1-12-05	Water Supply
7-03.1-12-06	Utensils and Equipment
7-03.1-12-07	Milking
7-03.1-12-08	Miscellaneous Equipment
7-03.1-12-09	Protection from Contamination
7-03.1-12-10	Handwashing Facility
7-03.1-12-11	Personal Cleanliness
7-03.1-12-12	Cooling
7-03.1-12-13	Milk Transporting Vehicles
7-03.1-12-14	Insect and Rodent Control
7-03.1-12-15	Pesticides and Adulterants
7-03.1-12-16	Milk Quality
7-03.1-12-17	Inspection and Enforcement Procedures - Farm Inspection

7-03.1-12-01. Abnormal milk.

1. Cows producing abnormal milk including lacteal secretions obtained within ninety-six hours of freshening (colostrum) should be milked last or with separate equipment and the milk discarded. Milk adulterated by chemical, medicinal, or radioactive materials, or milk obtained from cows less than ninety-six hours after calving, may not be stored in the milkroom or offered for sale.
2. Disease infected cows, or cows treated with chemicals or medicinals, and cows producing milk that is abnormal to sight or odor must be segregated from the milking herd or identified to prevent commingling with normal milk.

3. Milk from diseased, contaminated, or treated cows that is abnormal, adulterated, or unwholesome in nature, must be properly disposed of and may not be offered for sale or stored in the milkroom.
4. Equipment used to milk sick cows or from cows producing abnormal, adulterated, or unwholesome milk may not be stored in the milkroom, unless it meets all the construction, cleaning, sanitation, and storage requirements in section 7-03.1-12-06.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-02. Milking and cow area. A milking barn or parlor must be provided for the milking operations. At a minimum the milking area must meet all of the following requirements:

1. Have floors constructed of concrete or equally impervious material.
2. Have smooth, painted, or otherwise properly finished walls and ceilings that are in good repair, and the ceiling must be dusttight.
3. Separate stalls or pens for horses, calves, and bulls, if housed in the milking area.
4. Have the equivalent of ten foot-candles of natural or artificial light, well distributed for either day or night milking.
5. If feed is stored in or adjacent to, or fed in the milking area, it must have a dusttight covered storage facility.
6. Have sufficient space for milking operations and air circulation to prevent condensation and excessive odors.
7. Be kept clean and free of litter.
 - a. The floors, walls, ceiling, windows, pipelines, and equipment must be clean and free of filth.
 - b. Be free of swine and fowl, including excreta or waste materials.
8. At a minimum the cowyard must:
 - a. Be graded to drain and have no standing pools of water.

- b. Be cleaned and well maintained with no accumulations of organic wastes (a loafing or housing area with a manure pack will be in compliance from October first to June first, if properly maintained and clean bedding is added at sufficient frequency to prevent soiling of the cow. Manure packs may not be allowed between June first and September thirtieth).
- c. Not be accessible to swine or swine waste.
- d. Be free from the accumulation of waste feed. Manure is to be removed or properly stored at sufficient intervals so as to not be accessible to the cow.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-03. Milkhouse or milkroom. Except as provided in subsection 5 of section 7-03.1-12-06, a milkroom must be provided for the cooling, handling, and storing of milk and to conduct the washing, sanitizing, and storage requirements of the milk containers and utensils. The milkroom at a minimum must meet all the following requirements:

- 1. The floor must:
 - a. Be smooth and of concrete or equally impervious material.
 - b. Graded to drain.
 - c. Have drain trapped or screened.
- 2. Have walls and ceilings that are smooth and in good repair, and well painted or finished in an equally acceptable manner. All windows, doors, and hose ports must be in good repair to operate properly.
- 3. Have adequate lighting and ventilation.
 - a. An equivalent of twenty foot-candles must be provided in all working areas.
 - b. Ventilation must be provided to minimize odors and condensation.
 - c. All openings must be closed during dusty or windy weather.
 - d. Vents or light fixtures may not be placed over milk or utensil storage areas.
- 4. Other general requirements:

- a. Be of sufficient size and used only for approved milkhouse operations.
 - b. Have no direct openings into any barn, stable, or rooms used for domestic purposes except a tight-fitting door may be permitted if solid and self-closing.
 - c. Dispose of liquid waste in a sanitary manner.
 - d. Be equipped with a hose port.
 - e. Existing dairy farms must have an impervious slab at a minimum of three feet by three feet [.914 meters by .914 meters] in size to protect the milk hose on the outside of the milkroom under the hose port. After July 31, 1986, all new dairy farms must have a minimum hose port slab of six feet by six feet [1.83 meters by 1.83 meters].
 - f. A suitable shelter for the transportation truck if used for cooling and storing milk.
 - g. A double wash and rinse vat accessible for use and of adequate size.
 - h. Hot water heating capacities and temperature to match milkroom needs.
 - i. Adequate hot and cold water under pressure to provide the normal cleaning needs of the milkroom, utensils, and equipment.
5. Keep the floors, walls, ceiling, windows, tables, shelves, cabinets, wash vats, nonproduct contact surface of equipment, containers, and utensils clean.
 6. Must be used only for storage of articles and to conduct activities normal to the milkroom. Animals and fowl are not to be allowed in or housed in the milkroom.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-04. Toilet. Every dairy farm must have adequate toilet facilities and the facility must meet all the following requirements:

1. Be conveniently located for the convenience of workers involved in the dairy operation.
2. Be constructed to prevent human waste from polluting soil surfaces or contaminating any water supply, and operated to prevent access to insects.

3. Be kept clean and free of evidence of human waste.
4. Be operated in compliance with state requirements.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-05. Water supply. A safe water supply in compliance with state water requirements must be provided. At a minimum, the water supply must meet the following requirements:

1. Be constructed and operated in accordance with the state water requirements.
2. Be in compliance with state bacteriological requirements.
3. Be free of any cross connection or submerged inlets that could allow contamination of a water supply.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-06. Utensils and equipment. All utensils and equipment must be of a design approved by the dairy commissioner, constructed of materials known to be safe, and must be easily cleaned and sanitized.

1. Construction must be in compliance with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, where 3A sanitary standards have been adopted for dairy equipment. Where no standards exist, dairy commissioner approval is required.
2. The commissioner's approval must be based on meeting all the following requirements:
 - a. At a minimum, the equipment and utensils must be smooth, impervious, safe, and cleanable.
 - b. The equipment and utensils must be maintained in good repair and must be accessible for inspection. Where tools are required to gain access to equipment, the tools must be stored in the milkroom.
 - c. Single-service items must have been manufactured, packaged, transported, and handled in a sanitary manner. They must be stored in a manner to prevent contamination and may not be reused.

- d. Equipment design must be submitted to the dairy commissioner, prior to installation, for approval. Equipment not installed according to an approved plan must be corrected and brought into compliance within a time acceptable to the dairy commissioner.
 - e. Clean-in-place equipment must be installed to be self-draining. Gaskets or fittings must be self-positioned, smooth, and with flush interior surfaces. Requirements for clean-in-place systems are the same as stated in subdivisions a, b, and d.
3. The product contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk must be cleaned after each use.
 4. The product contact surface of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk must be cleaned after each use and sanitized before each use.
 5. All equipment, utensils, and articles, used in the milking operations must be stored in the milkroom. Additionally, all the following are required:
 - a. All multiuse equipment and utensils must be in a sanitizing solution or on racks in the milkroom until used, except milk lines and equipment designed and approved for use in the milking area, and clean-in-place cleanable, may be stored in the milking area if properly capped or protected.
 - b. Equipment when stored, unless in sanitizing solutions, must be stored to assure complete drainage.
 - c. Single-service items must be stored in their original container or other approved containers or cabinets to assure protection against contamination.
 6. After sanitation, all containers, utensils, and equipment must be handled in a manner to prevent contamination.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-07. Milking. Milking must be performed in a facility approved by the dairy commissioner and cows must be clean when milked. The requirements for milking are as follows:

1. The milking operation must be conducted in a parlor, stable, or barn.

2. If brushing is required, it must be completed prior to milking.
3. Cows must be clean at the time of milking and flanks, bellies, tails, and udders must be clipped as necessary to facilitate cleaning of these areas.
4. Teats and udders of milking cows must be cleaned and treated with a sanitizing solution and be relatively dry just prior to milking. Teats must be treated in an approved manner following milking to prevent the spread of mastitis.
5. Hand milking is prohibited, except in an emergency, and then, wet hand milking is prohibited.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-08. Miscellaneous equipment. All equipment necessary for the milking operation but not considered a part of the facility or milking equipment must be clean and properly stored when not in use. Milk stools, surcingles, and anti-kickers are to be kept clean and stored above the floor in either the milking area or milkroom, when not in use. Milk stools may not be padded and must be constructed to be easily cleanable.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-09. Protection from contamination. All milking equipment, milk handling equipment, containers holding milk, or items to be in contact with milk must be properly protected from contamination as follows:

1. Equipment and operations must be located so as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact. Openings must be covered or otherwise protected from sources of contamination.
2. All milk which has leaked, overflowed, been spilled, or improperly handled must be discarded.
3. Milk being offered for sale will immediately be stored in an approved bulk tank.
4. Milk must be transferred through approved equipment, pipelines, pails, or other containers adequately protected from contamination.

5. Air under pressure, used to agitate or move milk, or air directed at milk contact surfaces, must be free of oil, dust, rust, excessive moisture, extraneous material and odors, and must be properly filtered.
6. Antibiotics and medicinals must be stored in such a manner that they cannot contaminate milk or milk contact surfaces. Only medicines and chemicals recommended for use on lactating dairy cows may be stored in the milkroom.
7. During milking operations, pipeline and equipment used to contain or conduct milk must be effectively separated from tanks or circuits containing cleaning or sanitizing solutions, or other potential sources of adulterants.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-10. Handwashing facility. Every dairy farm must be equipped with an adequate handwashing facility. The handwashing facility must be conveniently located and accessible to the milkroom, milking area, and flush toilets. The handwashing facility must include an approved cleaning compound, hot and cold running water, individual sanitary towels, and a lavatory fixture. Utensil wash and rinse vats may not be used for handwashing.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-11. Personal cleanliness. Personnel involved in the milking operations or conducting operations in the milkroom, shall practice acceptable personal hygiene and shall be attired in clean garments. Hands must be washed, cleaned, and dried with an individual sanitary towel immediately before milking, and before performing any milking function. Milkers and persons utilizing the milkroom shall wear clean outer garments while milking or handling milk, milk containers, utensils, and equipment.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-12. Cooling. Every dairy farm must be equipped with a bulk tank of adequate capacity to hold all milk being offered for sale and the tank must meet 3A sanitary standards as follows:

1. Milk must be cooled to forty degrees Fahrenheit [4.4 degrees Celsius] or less within two hours after milking and blended

milk temperatures from subsequent milkings may not exceed fifty degrees Fahrenheit [10 degrees Celsius]. Raw milk must be forty-five degrees Fahrenheit [4.4 degrees Celsius] or cooler to be eligible for sale and transport off the farm.

2. Recirculated cold water used in precoolers or heat exchangers must be from a source determined safe by the dairy commissioner and adequately protected from possible contamination.
3. The volume of milk in the bulk tank after the first milking must reach the agitator to such a level that adequate agitation of the milk is possible. Failure to produce adequate volumes of milk on the first milking will result in loss of the producer's certification to sell raw milk.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-13. Milk transporting vehicles. Vehicles used to transport milk must be clean and constructed to protect the milk. Milk transporting vehicles must be clean both externally as well as in the milk contact surfaces of the tank, pump, and hose. The tank must be constructed to protect the milk from the sun, to maintain temperatures from the farm to the point of delivery between thirty-two and fifty degrees Fahrenheit [0 and 10 degrees Celsius], and to protect the milk from contaminations. Substances capable of contaminating or adulterating the milk may not be transported with the milk.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36, 4-30-38

7-03.1-12-14. Insect and rodent control. Effective measures must be taken to prevent the contamination of milk, containers, equipment, and utensils by insects or rodents as follows:

1. Fly breeding must be kept to a minimum.
 - a. Manure during fly breeding season (approximately June fifteenth) must be spread directly to fields or piled for not more than four days on the ground, or seven days in an impervious floored bin. Other satisfactory methods that will effectively control fly breeding may be approved by the dairy commissioner.
 - b. All manure packs must be well bedded and managed in a manner to prevent fly breeding.
2. Milkrooms must be effectively protected.

- a. Openings must be screened against the entrance of vermin.
 - b. The milkroom must be free of evidence of insects or rodents either present or having been present in the milkroom.
3. All surroundings to the dairy operations must be kept neat and clean and free of conditions known to harbor, or that are conducive to the breeding of, insects or rodents.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-15. Pesticides and adulterants. Chemicals used to control insects and rodents must be safe and used so as to not adulterate the milk supply. Only insecticides and rodenticides approved by the dairy department or registered and labeled for use in the dairy operation are allowed. Chemicals must be used in a safe manner according to manufactured label recommendation. Chemicals must be used in a manner that will not contaminate milk contact surfaces, the milk supply, or feed and water.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-16. Milk quality. The following chemical, physical, and bacteriological standards apply to Grade A raw milk for pasteurization:

Bacteria Limit: Milk may not exceed one hundred thousand per milliliters.

Somatic Cell: Milk may not exceed one million per milliliters.

Antibiotics: Milk may not equal or exceed a sixteen millimeters zone with the bacillus sterothermophilus disc assay method.

Pesticides: Milk may not exceed the established limits set by the environmental protection agency for any pesticides.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-12-17. Inspection and enforcement procedures - Farm inspections.

1. Farms scoring ninety-two or higher on farm inspections, with all violations on the preceding inspection corrected, must be inspected at a frequency of every four to six months.
2. Farms scoring between ninety-one and eighty-five, with all violations on the preceding inspections corrected, must be inspected at a frequency of every sixty to one hundred twenty days.
3. Farms scoring below eighty-five, or farms with two successive violations must be reinspected at a frequency of every fourteen to forty-five days.
4. Items for which the dairy commissioner has established a compliance deadline will be exempted until the deadline has expired.
5. Farms with three repeat violations of the same inspection line item, or that score seventy-nine or below, must be downgraded to manufacturing grade certification. The inspector shall notify the dairy commissioner, the milk plant, the milk hauler, and the producer of the status change.
6. A warning letter must be sent notifying the producer of intent to suspend the producer's permit any time two of the last four milk tests exceed the temperature, bacteria, or somatic cell limits, or when the same inspection item has been in violation on two consecutive inspections.
7. No sooner than three days nor later than twenty-one days following the warning for exceeding the bacteria or somatic cell requirements, the producer's milk must be resampled and tested to determine compliance. Should that sample test exceed the requirements, the producer's grade A certification must be suspended.
8. When any official test shows a producer's milk exceeds one million bacteria per milliliter of milk, the grade A certification must be immediately suspended, the producer's status changed to manufacturing grade, and the milk supply classified as undergrade.

When milk is in violation of antibiotic or pesticide limits, it must be excluded from all markets until test shows the supply to be in compliance.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-31, 4-30-36, 4-30-53

**CHAPTER 7-03.1-13
INSPECTION REQUIREMENTS FOR DAIRY
MANUFACTURING AND PROCESSING PLANTS**

Section	
7-03.1-13-01	Premises
7-03.1-13-02	Buildings
7-03.1-13-03	Facilities
7-03.1-13-04	Equipment and Utensils
7-03.1-13-05	Personnel - Cleanliness and Health
7-03.1-13-06	Using Farm Separated Cream in the Manufacturing of Butter

7-03.1-13-01. Premises.

1. **General requirements.** The premises must be clean, orderly, and free from strong odors, smoke, or air pollution. By July 1, 1991, traffic areas must be constructed of cement, asphalt, or hard surfaced material to keep dust and mud to a minimum.
2. **Surroundings.** Surroundings must be free from refuse, overgrown vegetation, and waste materials, and must be designed to prevent rodents, insects, and other vermin from harboring.
3. **Drainage.** The premises must provide a system which will allow rapid drainage of all water from plant buildings and driveways. Such water must be disposed of in a manner to prevent an environmental health hazard.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-34

7-03.1-13-02. Buildings.

1. **General requirements.** Buildings must be of sound construction, kept in good repair, and built to prevent rodent, bird, insect, and other harmful animal harborage. Service pipe openings in buildings must be sealed or provided with tight metal collars.
2. **Outside doors, windows, and other openings.**
 - a. All outer openings must be effectively screened to prevent insect, rodent, dust, and dirt from entering.

- b. All outside door openings must be self-closing into processing areas. If screened, they must be of sound construction.
- c. All hinged, outside screen doors must open outward and be self-closing and insect tight. All doors and windows must be kept clean and repaired.
- d. Outside conveyor openings must be constructed to prevent entrance of flies and rodents.
- e. Outside openings for sanitary pipelines must be covered when not in use.
- f. On new construction, window sills must slant downward at a forty-five degree angle.

3. Walls, ceilings, partitions, and posts.

- a. All must be smoothly finished with suitable light color, moisture impervious material, and kept clean.
- b. New construction must have rounded corners at the juncture of the wall and floor in all areas.

4. Floors. Floors must be laid with impervious joint material, concrete, or other impervious material and must be smooth, kept in good repair, and graded to drain (all drains must be equipped with traps). The plumbing must be so installed as to prevent sewage backup into drain lines and to the floor of the plant. Old storage rooms of product and starter rooms need not be provided with floor drains if the floor is sloped to drain to an exit. Sound, smooth, wood floors which can be kept clean may be used in rooms where containers and supplies are stored.

5. Lighting.

- a. It must be ample and natural or artificial.
- b. Thirty foot-candles are required in:
 - (1) Rooms where products are manufactured or packaged.
 - (2) Rooms where utensils are washed.
 - (3) Restrooms and locker rooms.
- c. Fifty foot-candles are required in:
 - (1) Rooms where dairy products are graded.

(2) Rooms where products are examined for condition and quality.

d. Other rooms need ten foot-candles when measured at a distance of thirty inches [76.2 centimeters].

e. Where contamination of product by broken glass is possible, light bulbs and fluorescent tubes must be protected against breakage.

6. Ventilation.

a. Adequate heating, ventilation, or air-conditioning is required for all rooms and compartments to permit maintenance of sanitary conditions.

b. Inlet fans must be provided with an adequate air filtering device to eliminate dirt and dust from incoming air.

c. Ventilation systems must be periodically cleaned and repaired.

d. Exhaust outlets must be screened or provided with self-closing louvers to prevent the entrance of insects when not in use.

7. Rooms and compartments.

a. General.

(1) Rooms and compartments must be so designed, constructed, and maintained to assure desirable room temperatures, must be clean and in orderly operating condition, and must be free from objectionable odors and vapors.

(2) Bulk milk receiving rooms must be separated from processing rooms by a wall.

(3) Processing rooms must be kept free of extraneous equipment and materials not involved in the processing.

b. Coolers and freezers must be:

(1) Clean.

(2) Dry.

(3) Maintained at proper uniform temperatures and humidity.

(4) Equipped with adequate air circulation.

- (5) Free from rodents, insects, and other vermin.
- (6) Equipped with clean dry shelves where applicable.
- (7) Equipped with refrigeration units that have provisions for collecting and disposing of condensate.

A thermometer is required at the entrance to all coolers where finished dairy products are stored.

c. Supply rooms and storage rooms must be:

- (1) Clean, dry, and orderly.
- (2) Free of insects, rodents, and other vermin.
- (3) Maintained and repaired.

d. Food ingredients and packaging materials stored in supply rooms and storage rooms must be protected from dust, dirt, or other extraneous material, and must be so arranged on racks, shelves, or pallets to permit access to supplies and cleaning and inspection of the room. A twelve-inch [30.48 centimeters] distance must be maintained between the supply storage room wall and the products to be stored. Nonfood items (i.e., cleaning compounds) must be stored in a separate room or in a closed cabinet away from the food items or packaging supplies.

e. Boiler and shop rooms must be separated from processing areas, packaging areas, or storage areas and must be orderly and reasonably free from dust and dirt.

f. Toilet and dressing rooms.

- (1) They shall be conveniently located.
- (2) The toilet room may not directly open into processing packaging or storage areas.
- (3) The doors must be self-closing.
- (4) They must be vented to the outside air and vents kept clean and repaired.
- (5) Locker rooms must be kept clean, free, and orderly.
- (6) There must be adequate handwashing facilities.
- (7) Signs must be posted conspicuously directing employees to wash their hands before returning to work.

- g. Laboratories in all rooms and compartments must meet requirements of North Dakota Century Code section 4-30-18. Any deviation from these requirements will only be allowed with approval of the dairy commissioner.
- h. Starter facilities must be adequate and not located near areas where contamination is likely to occur. Positive ventilation, light colored walls, and concrete floors are required.
- i. Grading and inspection room.
 - (1) When grading and inspection of product is performed, there must be a room or appropriate area specifically designated for this.
 - (2) The product to be graded or inspected shall be tempered in accordance with United States Department of Agriculture requirements in a room or area kept at not less than sixty degrees Fahrenheit [15.55 degrees Celsius].
 - (3) The room must have a table or desk and convenient handwashing facilities. It must be clean, dry, free from foreign odors, and free from distracting elements.
- j. Resident inspectors facilities must include:
 - (1) A conveniently located, adequate sized, well-lighted, vented or air-conditioned and heated office.
 - (2) A desk.
 - (3) A lockable storage supply cabinet.
 - (4) A clothes locker.
- k. Lunchrooms and eating areas:
 - (1) Must be kept clean and orderly.
 - (2) May not open directly into processing or packaging areas.
 - (3) Must have signs posted directing employees to wash hands before returning to work.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-34

7-03.1-13-03. Facilities.

1. Water supply in facilities must comply with all of the following requirements:
 - a. Ample supply of hot and cold running water.
 - b. Safe and sanitary in quality.
 - c. Protected against contamination.
 - d. No cross connections.
 - e. Bacteriological examination of plant's water supply must be taken at least twice a year, or more frequently when necessary, and records kept on file.
 - f. Well construction; location, and operation must be approved by the dairy commissioner.
2. Drinking water facilities must be sanitary and conveniently located.
3. Handwashing facilities must have:
 - a. Hot and cold running water.
 - b. Soap.
 - c. Sanitary single-service towels or air dryers.
 - d. Convenient access, located in processing rooms, toilets, locker rooms, and other essential areas in plant.
 - e. Containers provided for towels and other waste material. They must be metal, plastic, disposable or reusable, and have self-closing covers.
4. Steam must be supplied in sufficient volume and pressure for operation. Culinary steam in contact with milk or dairy products must be free of harmful substances. Only boiler water additives meeting requirements of 21 CFR 121.1088 or a secondary steam generator using only soft water without use of boiler compounds is allowed.
5. Air under pressure must comply with 3A sanitary standards and practices as defined in North Dakota Century Code section 4-30-01.
6. Disposal of wastes requirements.
 - a. Wastes must be properly disposed of in accordance with the environmental protection agency requirements. Minimum

waste line size must be four inches [10.16 centimeters] on new construction or another size approved by the dairy commissioner.

- b. Sewer systems must be of sufficient slope and capacity.
- c. Where public sewer is not available, wastes must be disposed of in a manner not to contaminate equipment or create a nuisance or public health hazard. These systems must be approved by the dairy department prior to installation.
- d. Containers for collection must be metal, plastic, or other impervious material and covered with a tight-fitting lid.
- e. Wastes must be stored in an area or room to protect the room from flies and vermin.
- f. Solid waste must be disposed of regularly and containers cleaned before reuse.
- g. Cardboard and other paper waste must be kept to a minimum and disposed of acceptably.
- h. Sanitary sewers may not be located directly above milk or milk product storage facilities or processing facilities.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-34

7-03.1-13-04. Equipment and utensils.

1. General requirements.

- a. All equipment and utensils must be readily dismountable for cleaning, sanitizing, and for inspection.
- b. All product contact surfaces shall be stainless steel, meet 3A sanitary standards as defined in North Dakota Century Code section 4-30-01, or be approved by the dairy commissioner.
- c. Nonmetallic parts other than glass must meet 3A sanitary standards as defined in North Dakota Century Code section 4-30-01 for plastic, rubber, and rubberlike material.
- d. Equipment and utensils for cleaning must be in acceptable condition, i.e. not rusty, pitted, or corroded.
- e. All equipment and piping must be kept in good repair and free from cracks and corroded surfaces.

- f. New or rearranged equipment must be set away from the wall or spaced to facilitate good housekeeping and cleaning. Major changes in plant operations due to new or rearranged equipment should be approved by the dairy commissioner.
 - g. All product contact parts and piping must be reasonably accessible for inspection except those carrying only clean-in-place solution.
 - h. Dairy product pumps must be sanitary and easily dismantled or of specially approved construction to allow effective cleaning in place.
 - i. Clean-in-place systems must comply with 3A sanitary standards as defined in North Dakota Century Code section 4-30-01 and be equipped with recording thermometers.
2. Receiving tanks must comply with 3A sanitary standards, must be easily accessible for cleaning inside and out, must be elevated above the floor, and must be protected sufficiently with covers or baffles to prevent contamination. When necessary to provide easy access to cleaning of floors and walls, receiving tanks must be equipped with wheels or casters.
3. Product storage tanks or vats.
- a. Product storage tanks or vats must be fully enclosed or tightly covered, must be well insulated, and the entire inside surface as well as agitators and all other appurtenances must be accessible for cleaning and inspection.
 - b. Any opening at the top of the vat or tank including shaft entrance must be protected against entry of dust, dirt, and grease.
 - c. Sight glasses must be sound, clear, and in good repair.
 - d. Vats with hinged covers must be easily cleanable and designed for protection of dust or moisture entering the product when the lid is opened.
 - e. In cases of air agitation, systems must be 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, approved.
 - f. Vats holding products at least eight hours must be equipped with adequate insulation and adequate refrigeration. Ice cream and other frozen desserts must be refrigerated a maximum of zero degrees Fahrenheit [minus 17.77 degrees Celsius]. Cheese, liquid milk and other processed dairy products must be refrigerated a

maximum of thirty-two to forty-five degrees Fahrenheit [0 to 7.22 degrees Celsius].

- g. All tanks or vats must comply with 3A sanitary standards as defined in North Dakota Century Code section 4-30-01 or state-approved standards and must be equipped with thermometers in working order, which are tested for accuracy semiannually.
4. All product contact surfaces of separators must be stainless steel and free of rust or pits. All separators must be 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, approved or acceptable to the dairy commissioner.
5. Dome-type batch pasteurizers must be stainless steel and nonmetallic parts must comply with 3A standards as defined in North Dakota Century Code section 4-30-01. Each pasteurizer used for heating products at a temperature of five degrees Fahrenheit [minus 15 degrees Celsius] or more above the minimum pasteurization temperature need not have an airspace heater. Each pasteurizer must, however, be equipped with an airspace thermometer to ensure a temperature at least five degrees Fahrenheit [minus 15 degrees Celsius] above that required for pasteurization of the product and must have an adequate means of controlling the heating medium. Dome-type batch pasteurizers must have temperature indicating and recording devices which will be checked by the dairy department a minimum of every six months.
6. High temperature short time pasteurizing systems.
 - a. When pasteurization is intended or required, all the following must be present:
 - (1) An approved timing pump or device.
 - (2) A recorder controller.
 - (3) Flow diversion valve or valves.
 - (4) A holding tube.
 - (5) A plate type or internal tubular heat exchanger.
 - b. The entire system must comply with 3A sanitary standards as defined in North Dakota Century Code section 4-30-01 and must be checked by the dairy department a minimum of every six months.
 - c. After the pasteurization unit has been checked, the timing pump or timing system, flow diversion valves, and recorder controller must be sealed in accordance with 3A sanitary

standards as defined in North Dakota Century Code section 4-30-01 and state standards. It shall be the responsibility of the plant to notify the dairy commissioner immediately of any broken seals on high temperature short time equipment.

- d. When direct steam pasteurizers are used, the steam strainer and steam purifier with a steam trap are required, and the steam must be of culinary quality.

7. Thermometers and recorders.

- a. Indicating thermometers must be long stem, accurate within five-tenths degrees Fahrenheit [0.27 degrees Celsius] and for the applicable temperature range, and provide for checking of temperature of pasteurization, cooling of products, and the accuracy of recording thermometers.
- b. Short stem indicating thermometers must be accurate within five-tenths degrees Fahrenheit [0.27 degrees Celsius] for the applicable temperature range, and installed in the proper stationary position.
- c. Storage tank thermometers, when required, must have a plus two degree accuracy.
- d. Airspace indicating thermometers, when required must be accurate within one degree Fahrenheit [0.55 degrees Celsius], and must be installed above the surface of the products pasteurized in the vat (a minimum of one inch [2.54 centimeters]) to make sure the temperature of foam or air, or both, above the products pasteurized also receives the required treatment.
- e. Recording thermometers.
 - (1) Recording thermometers must be accurate within plus one degree Fahrenheit [1.11 degree Celsius] for the applicable temperature range, and must be used on each heat treating, pasteurizing, or thermal processing unit to record the heating process.
 - (2) Additional use of recording thermometers must be accurate within plus one degree Fahrenheit [1.11 degree Celsius] when a record of temperature or time of cooling and holding is of significant importance.
 - (3) Charts must be marked to show:
 - (a) Date.
 - (b) Plant identification.

- (c) Reading of indicating thermometer at a particular referenced point.
 - (d) Name of product pasteurized, amount of product pasteurized or flow rate, and length of time product pasteurized.
 - (e) Cut-in and cut-out on high temperature short time system.
 - (f) Record of forward and divert flow on high temperature short time systems.
 - (g) Airspace temperature (when applicable).
 - (h) A record of any unusual occurrences on chart.
8. Surface coolers.
- a. Surface coolers must be equipped with hinged cover and removable cover.
 - b. Edges of the fins must be so designed to divert condensate on nonproduct surfaces away from product contact surfaces.
 - c. All gaskets or swivel connections must be leakproof.
9. Plate heat exchangers.
- a. Plate heat exchangers must comply with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, when applicable.
 - b. Gaskets must be tight and in good operating order.
 - c. Plates must be opened for inspections by the operator at frequent intervals to determine if equipment is clean.
 - d. A cleaning regime must be posted.
10. Internal tubular heat exchangers must comply with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, when applicable.
11. Pumps when applicable, must comply with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, and must be disassembled and cleaned manually after each use unless specifically designed for effective cleaning-in-place.
12. Scales must be inspected by the North Dakota department of weights and measures, yearly, and must be sealed.

13. Homogenizers must comply with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, or United States department of agriculture standards, when applicable and must be disassembled and cleaned daily after use unless designed for effective cleaning in place.
14. New equipment and replacements must comply with 3A standards and, where there are no 3A standards, as defined in North Dakota Century Code section 4-30-01, available, must meet the approval of the dairy commissioner. Also, only materials that are sanitary, readily cleanable, and nontoxic may be used for product contact surfaces, parts, and gaskets.
15. Vacuumizing equipment.
 - a. Vacuumizing equipment must be used for flavor control and water removal. It must be made of stainless steel or other equally corrosion-resistant material, constructed to facilitate cleaning, and accessible for inspection. It must be isolated by a vacuum breaker and positive activated check valves on the inlet and discharge sides when located on the pasteurized side of the unit.
 - b. If direct steam is used, it must be equipped with a ratio controller to regulate the composition when required to finish product, it must be of culinary quality, and it must have incoming steam supply regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow diversion device is not in the forward flow position.
 - c. Condensers, when used, must be equipped with a water level control and an automatic safety shutoff valve.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-34

7-03.1-13-05. Personnel - Cleanliness and health.

1. Cleanliness requirements.

- a. All employees shall wash hands upon returning to work from:
 - (1) Using toilet facilities.
 - (2) Eating.
 - (3) Smoking.
 - (4) Otherwise soiling their hands.

- b. All employees must keep hands clean and follow good hygiene practices while on duty.
- c. Expectorating (spitting) or use of tobacco is prohibited in areas where milk or milk products are handled in any way.
- d. The following items must be worn by all persons engaged in receiving, testing, processing, manufacturing, packaging, or handling dairy products:
 - (1) Clean, white or light colored, washable or disposable outer garments.
 - (2) Caps (paper caps, hard hats, or hair nets).
 - (3) Beard nets (males).

2. Health.

- a. No person with a communicable disease may be permitted in any rooms where milk and milk products are handled in any way.
- b. No person with an open discharging or infected wound on arms, hands, or on the exposed body parts may work in any dairy processing rooms or in any capacity resulting in contact with milk.
- c. At time of employment, each employee involved in processing, manufacturing, packaging, or handling dairy products, must certify that the employee is free of any communicable disease. This information must be kept on file at the dairy plant. It must be made available to the dairy commissioner upon request.
- d. An employee returning to work following illness from a communicable disease must have a certificate from the attending physician to establish proof of complete recovery. The record of a medical physical examination following illness from a communicable disease must be kept on file at the dairy plant and must be made available to the dairy commissioner upon request.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-34

7-03.1-13-06. Using farm separated cream in the manufacturing of butter. Farm separated cream may be used to manufacture butter, provided the cream is:

1. Received and stored in containers separated from cream produced in compliance with the state's manufacturing milk requirements.
2. Following the manufacturing of butter containing farm separated cream, the equipment is completely washed and sanitized before butter made from cream meeting the manufacturing milk requirements is manufactured into butter.
3. Butter made from farm separated cream is identified and stored in a manner acceptable to the dairy commissioner to ensure identity and separation from butter products manufactured in compliance with United States department of agriculture requirements.
4. In the final form when sold to the consumers, the products must be labeled in a manner not to confuse the product with United States department of agriculture approved or graded product, and the label must be approved by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-33, 4-30-35, 4-30-45

CHAPTER 7-03.1-14 INSPECTION CRITERIA FOR GRADE A PLANTS

Section

7-03.1-14-01	Floors
7-03.1-14-02	Walls and Ceilings
7-03.1-14-03	Doors and Windows
7-03.1-14-04	Lighting and Ventilation
7-03.1-14-05	Rooms
7-03.1-14-06	Toilet Facilities
7-03.1-14-07	Water Supply
7-03.1-14-08	Handwashing Facilities
7-03.1-14-09	Milk Plant Cleanliness
7-03.1-14-10	Sanitary Piping
7-03.1-14-11	Construction and Repair of Containers and Equipment
7-03.1-14-12	Cleaning and Sanitizing of Containers and Equipment
7-03.1-14-13	Storage of Cleaned Containers and Equipment
7-03.1-14-14	Storage of Single-Service Containers, Utensils, and Materials
7-03.1-14-15	Protection from Contamination
7-03.1-14-16	Pasteurization
7-03.1-14-17	Cooling of Milk
7-03.1-14-18	Bottling and Packaging
7-03.1-14-19	Capping
7-03.1-14-20	Personnel Cleanliness
7-03.1-14-21	Vehicles

7-03.1-14-01. Floors.

1. The floors of all rooms in which milk is handled, processed, or stored or in which milk containers or utensils are washed must be concrete, impervious tile, or brick laid with impervious joint material, metal surfacing with impervious joint material, or other material which is the equivalent of good quality concrete. The floors must be provided with drains, smooth, have no pooled water, and must be sloped.
2. The floors of storage rooms for dry ingredients or packaging material may be constructed of tightly joined wood and without drains.
3. Cold storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to one or more exits.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-02. Walls and ceilings. Walls and ceilings must be finished with smooth, washable, light-colored painted wood, tile, smooth surface concrete, cement plaster, brick, or other equivalent materials with washable light-colored surface. Walls, partitions, windows, and ceilings must be kept in good repair and refinished as often as the finish wears off or becomes discolored.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-30

7-03.1-14-03. Doors and windows.

1. All openings to the outer air must be effectively protected by any of the following:
 - a. Screening.
 - b. Effective electric screen panels.
 - c. Fans or air curtains to provide sufficient air velocity.
 - d. Properly constructed flaps where it is impractical to use self-closing doors or air curtains.
 - e. A combination of subdivisions a, b, c, and d.

2. All openings to the outer air must be ratproof to the extent that is necessary to prevent rodent entry.
3. Outer doors must be self-closing. Screen doors must open outward.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-04. Lighting and ventilation.

1. Lighting requirements.

- a. Adequate light sources are required (natural, artificial, or combination) which must furnish at least twenty foot-candles to all areas where milk and milk products are handled, processed, or stored or where utensils, containers, or equipment are washed.
- b. Dry storage areas must be provided with at least five foot-candles of light.

2. Ventilation requirements.

- a. Small rooms must be kept reasonably free of odors and excessive condensation on equipment, walls, and ceilings.
- b. Pressurized ventilating systems, if used, must have a filtered air intake.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-05. Rooms.

1. Processing, pasteurizing, cooling, and packaging must be conducted in single rooms but not in the same room as cleaning of cans, bottles, and cases or the cleaning and unloading of milk truck tanks.
2. Cooling may be done in the room where milk tank trucks are unloaded or cleaned and sanitized.
3. Facilities for cleaning and sanitizing of milk tank trucks must be equipped for manual or mechanical operations. If facilities are not on plant premises they must be performed at receiving stations, transfer stations, or separate washing installations.

4. Rooms must be of sufficient size for their intended purpose.
5. Rooms in which milk or milk products are handled, processed, or stored or where equipment utensils and milk containers are washed or stored, may not directly open into stables or rooms used for domestic purposes.
6. All bulk milk storage tanks must be vented into a room used for pasteurization, processing, cooling, packaging operations, or into a storage tank gallery room. Vents may be located elsewhere, if they are adequately equipped with air filters so as to preclude the contamination of the milk.
7. Solid doors in required partitions must be self-closing.
8. Cottage cheese rooms.
 - a. New cottage cheese vat installations must be located in a separate room maintained free of vermin and flies, and must be kept clean.
 - b. Existing installations will be allowed in the processing room provided there is no evidence of overcrowding, excessive traffic, condensation, or splash, and provided they are equipped with multiservice, or single-service covers which must be kept in place at all times during the setting operation.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-06. Toilet facilities.

1. The milk plant must be provided with facilities conforming with the applicable provisions of the state or local plumbing code.
2. Toilet rooms may not open directly into any room in which milk or milk products are processed. They must be completely enclosed and have tight-fitting self-closing doors.
3. Dressing rooms and fixtures must be kept in clean condition and good repair and must be well lighted and ventilated, have toilet tissue, and have an easily cleanable covered waste receptacle.
4. Sewage and other liquid wastes must be disposed of in a sanitary manner. Nonwater carried sewage disposal facilities may not be used.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-36

7-03.1-14-07. Water supply.

1. Municipal water systems must be from an adequate supply, protected and operated. They must be easily accessible and safe as approved by the state water control authority.
2. Individual water systems must be constructed and operated in compliance with the state water requirements. They must also be free of any cross connection or submerged inlets that could allow contamination of a water supply.
3. There must be no cross connections between safe and unsafe water sources.
4. An airgap or effective back-flow preventer must be on all connections between the water supply piping and a makeup tank (such as for cooling and condensing).
5. Condensing water and vacuum water must meet the requirements of subsections 1 through 4. In specific cases where the water does not meet these requirements, the water may be used so long as the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of the equipment or its contents. This is accomplished by use of a surface-type condenser or use of reliable safeguards to prevent the overflow of condensing water from the condenser.
6. Condensing water and reclaimed water from milk or milk products may be reused when in compliance with the requirements of this section and when proper protection from contamination is used.
7. Water systems which have been repaired or otherwise contaminated must be disinfected before use and then pumped free of disinfectant before bacteriological testing.
8. Regulatory bacteriological testing must occur:
 - a. Upon initial approval.
 - b. Once every six months after approval.
 - c. Upon notification of repair or alteration of water system.

Regulatory bacteriological testing must be conducted at an official laboratory, and must be on record and retained at the dairy department.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-08. Handwashing facilities. Handwashing facilities must be conveniently located to toilets and rooms in which milk plant operations are conducted and must be clean and in good repair, and must have hot and cold or warm running water, soap, and individual sanitary towels or approved handdrying devices. Steam-water mixing valves and vats for washing bottles, cans, and similar equipment may not be used as handwashing facilities.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-09. Milk plant cleanliness.

1. All piping, floors, walls, ceilings, fans, shelves, tables, and the nonproduct contact surfaces of facilities and equipment must be clean.
2. All rooms in which milk and milk products are handled, processed, or stored or in which containers, utensils, or equipment are washed or stored, must be kept clean, neat, and free of evidence of insects and rodents.
3. Only equipment directly related to processing operations or the handling of containers, utensils, and equipment is permitted in the pasteurizing, processing, cooling, packaging, and bulk milk storage rooms.
4. No trash or solid waste may be stored within the plant except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during operation of such equipment.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-10. Sanitary piping.

1. All sanitary piping, fittings, and connections which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk products must consist of smooth impervious, corrosion-resistant, nontoxic, easily cleanable material consisting of one or more of the following:

- a. Stainless steel of the American iron and steel institute 300 series.
 - b. Equally corrosion-resistant metal (to subsection a) which is nontoxic and nonabsorbent.
 - c. Heat-resistant glass.
2. Plastic, rubber, or rubberlike materials used for gaskets, sealing applications, short plastic take down jumpers, or connections where flexibility is required for essential or functional reasons must be:
 - a. Relatively inert.
 - b. Resistant to scratching, scoring, decomposition, crazing, chipping, and distortion.
 - c. Nontoxic.
 - d. Fat resistant.
 - e. Relatively nonabsorbent.
 - f. Constructed of a material which does not impart flavor or odor to the product.
 3. The piping, fittings, and connections must be designed, constructed, and installed to be easily cleaned, kept in good repair, free of breaks or corrosion, to contain no dead ends of piping, and to allow drainage, and inspection.
 4. Cleaned-in-place milk pipelines and return solution lines must be rigid, self-draining, and so supported to maintain uniform slope and alignment.
 5. Gaskets, if used, must be self-positioning, designed, finished, and applied to form a smooth, flush interior surface. If gaskets are not used, fittings must have self-positioning faces designed to form smooth, flush interior.
 6. Pipelines.
 - a. Interior of welded joints must be free of pits, cracks, or inclusions.
 - b. Pipelines must be inspected by a borescope or other appropriate inspection device.
 - c. Pipelines must have access points for inspection and be approved by the dairy commissioner.

- d. Plans for welded pipelines and any changes in these plans must be approved in writing by the dairy commissioner prior to construction.
7. Milk and milk products must be conducted from one piece of equipment to another only through sanitary piping. In the case of cottage cheese dressing or cheese, ingredients may be transported by other methods which protect the product from contamination.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-11. Construction and repair of containers and equipment.

1. Multiuse containers and equipment with which milk and milk products come into contact must be:
 - a. Smooth.
 - b. Impervious.
 - c. Corrosion resistant.
 - d. Nontoxic.
 - e. Stainless steel, of equally corrosion-resistant metal which is nontoxic and nonabsorbent; or heat-resistant glass, or plastic or rubber and rubberlike material that is inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion, nonabsorbent, nontoxic and resistant, does not impart flavor or odor to the product, and maintains original properties under repeated use.
2. Joints in containers, equipment, and utensils must be flush and finished as smooth as adjoining surfaces.
3. Rotating shaft inserted through a surface which milk or milk products come into contact. The joint between the moving and stationary surfaces must be close fitting.
4. A pressure tight seal must be provided ahead of all threads and crevices when thermometers or temperature sensing elements are inserted through a surface with which milk and milk products come into contact.

5. Openings in covers of tanks, vats, separators, and other containers and equipment must be protected by raised edges or otherwise to prevent the entrance of surface drainage.
6. Condensation diverting aprons must be provided as close as possible on all pipes, thermometers, and other equipment unless a watertight joint is provided.
7. All surfaces with which milk or milk products come into contact must be easily accessible or demountable for manual cleaning.
8. All product contact surfaces must be accessible for inspection and self-drainage.
9. There must be no threads used in contact with milk or milk products except where needed for functional or safety reasons and these must be of a sanitary type.
10. All multiuse containers and other equipment must have rounded corners, be in good repair, and free from breaks, crevices, and corrosion. Milk cans must have umbrella type covers.
11. Strainers must be self-draining and of approved design. The design must be perforated metal design. Strainers must use single-service strainer media. When required for functional reasons inherent to production of certain milk products, multiuse woven material may be used where it is impractical to use perforated metal. This must be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.
12. Single-service articles must be approved and not reused. They must be nontoxic and handled in a sanitary manner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-12. Cleaning and sanitizing of containers and equipment.

1. Containers and equipment must be thoroughly cleaned after each use and all equipment must be thoroughly cleaned at least once each day.
2. Storage tanks must be cleaned when emptied and must be emptied once every seventy-two hours. Tanks holding milk longer than twenty-four hours must be equipped with a seven-day temperature recording device.

3. Milk tank trucks must be cleaned and sanitized as required by the regulatory agency. Trucks must bear a tag or have a record showing the date, time, place, and signature or initial of the operator, unless the truck delivers to only one receiving unit where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag must be removed where the truck is next washed and sanitized and kept on file for fifteen days.
4. Pipelines and equipment designed for mechanical cleaning must have an effective cleaning and sanitizing regimen, a temperature recording device in the return solution line, and temperature recording charts identified, dated, and retained for three months. Charts are to be checked by the dairy commissioner on each official inspection.
5. Plants which manually clean containers must be equipped with a two compartment wash and rinse vat. A third treatment vat, steam cabinet, or individual steam jet plate with hood must be provided for sanitizing.
6. All multiuse containers, equipment, or containers must be sanitized prior to use. Tests to determine the efficiency of sanitation should be made by the dairy department.
7. The residual bacteria count of multiuse containers may not exceed one per milliliter of capacity (rinse test) and fifty colonies per eight square inches [51.61 square centimeters] of product-contact surface (swab test). Multiuse containers must be free of all coliforms. If fabricated in another plant and the regulatory agency has information that they do comply, the agency may accept the containers as being in conformance without additional tests unless they have reason to believe there is a conformance problem or bacterial problem.
8. The closure must be single service.
9. The container may not impart into the product pesticide residual levels or other contaminants in excess of acceptable limits.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-13. Storage of cleaned containers and equipment.

1. All multiuse containers, equipment, and utensils, after cleaning, must be transported and stored inverted on metal racks or in clean nonabsorbent, corrosion-resistant, nontoxic cases elevated above the floor or otherwise protected from contamination.

2. Floors may not be flushed or washed when crates of clean bottles are stacked on them.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-14. Storage of single-service containers, utensils, and materials.

1. Single-service caps, cap stock, parchment paper, containers, gaskets, or other single-service articles for use on contact with milk and milk products must be purchased and stored in sanitary tubes, wrappings, or cartons, kept clean and dry until used, and handled in a sanitary manner.
2. Paperboard shipping containers used to enclose plastic bags or unfilled containers must be used only once.
3. Spilled caps, gaskets, or parchment paper may not be refilled into their original container.
4. Cartons or boxes from which contents have been partially removed must be kept closed.
5. Caps, closures, or containers must be protected from contamination.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-15. Protection from contamination.

1. Equipment and operations must be located so to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.
2. Pipelines and equipment used to contain or conduct milk must be separated from tanks or circuits containing cleaning or sanitizing solution.
3. Milk and milk products which have overflowed, leaked, spilled, or been improperly handled must be discarded.
4. Milk and milk products drained from processing equipment at the end of a run, or collected from defoamers which do not return product to the filler bowl, or milk solids rinsed from equipment, containers, or pipelines, must only be repasteurized if they are handled sanitarily and kept at

forty-five degrees Fahrenheit [7.22 degrees Celsius] or less, otherwise they are to be discarded.

5. Returned package milk may not be repasteurized unless the product has been pasteurized at another grade A plant, handled in a sanitary manner, and maintained at forty-five degrees Fahrenheit [7.22 degrees Celsius] or less.
6. All product surfaces must be covered or otherwise protected from dust, insects, condensation, or contamination.
7. All openings attached to milk storage and milk tank trucks, pumps, vats, etc. must be capped or otherwise protected.
8. Unloading at transfer receiving stations or pasteurization plants, the following conditions must be met:
 - a. If the area is completely enclosed and the dust cover or dome and manhole cover opened slightly and held by metal clamps, a filter is not required.
 - b. If a dust cover or manhole is open in excess of what is allowed by the metal clamps, or the covers are removed, a filter is required for the manhole.
 - c. If areas are not enclosed or doors are open during unloading, a suitable filter is required.
 - d. Direct connections from truck to truck must be valve to valve or through the manhole lid, provided that all connections are made from ferrule to ferrule with protection for the air vent.
 - e. Receiving and dump vats must be completely covered, except during washing and sanitizing and when milk is being dumped. Openings in vats for strainers shall have covers designed to cover the opening with the strainer in place.
9. Whenever air under pressure is used in a manner to be in contact with milk and contact surfaces of milk equipment, it must be free of oil, free of dust, excessive moisture, extraneous material, and odor.
10. Steam containing toxic substances is prohibited and when used must be of culinary quality.
11. Standardization must be done before pasteurization is started unless pasteurized milk or milk products are used for standardization. In no case may raw milk be used to standardize pasteurized products unless the product is subsequently repasteurized. Standardization of grade A products with any milk or milk products other than grade A is prohibited.

12. Processing of food and drinks other than grade A milk and milk products must be performed to preclude the contamination of milk and milk products.
13. Means must be provided to prevent contamination of milk containers, utensils, and equipment.
14. All ingredients and nonproduct contact materials used in the preparation or packing of milk and milk products must be stored in a clean place, free from contamination.
15. Pasteurized milk may not be strained or filtered except through a perforated metal strainer.
16. Only those poisonous or toxic materials necessary for the maintenance of the dairy plant may be present in the dairy plant. These may not be stored in any room or area where they could contaminate product equipment, containers, utensils, etc., but must be in a separate room and distinctly labeled.
17. Only insecticides and rodenticides approved by the dairy commissioner may be used. They must be used in accordance with the manufacturers' label directions. They may not be used to contaminate milk, containers, equipment, and utensils.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-16. Pasteurization.

1. Batch.

- a. The pasteurizer must be designed so that the difference in temperature between the milk product in the center and the coldest milk in the vat will not exceed one degree Fahrenheit [0.55 degrees Celsius] at any time. The vat must be provided with adequate agitation with the agitator sufficiently submerged.
- b. Location and required readings of indicating and recording thermometers.
 - (1) Each batch pasteurizer must be equipped with both an indicating and recording thermometer.
 - (2) The thermometer may not read less than required pasteurization temperatures throughout the holding period. Temperatures of both thermometers must be checked by the plant operator and comparison must be on the recording chart.

- (3) The recorder may not read higher than the indicating thermometer.
 - (4) No batch of milk or milk products may be pasteurized unless it is sufficient to cover both thermometer bulbs.
- c. Batch pasteurizers must be so operated that in all circumstances milk and milk products will be held at not less than the minimum pasteurization temperature continuously for at least thirty minutes.
 - d. When filling or emptying temperatures are included in the time interval on the recording chart, such intervals must be indicated on the chart by the operator.
 - e. In batch pasteurizers the temperatures of the atmosphere above the milk and milk products may not be less than five degrees Fahrenheit [2.75 degrees Celsius] higher than legal pasteurization temperature. The pasteurizer must be equipped with an airspace thermometer, the surface of the milk must be at least one inch [25.4 millimeters] below the thermometer bulk, and this temperature must be inscribed on the recording chart each time the pasteurizer is in use.
 - f. Design and installation of valves and connections.
 - (1) Design and installation of valves and connections must meet requirements of section 7-03.1-14-10.
 - (2) All pipelines and fittings must be so constructed and so located that leakage will not occur.
 - (3) All single-leak grooves and all mating-leak grooves when matted must extend throughout the entire depth of the seat. Leakage must be diverted, drainage promoted, and air binding prevented.
 - (4) A stop must be provided on all plug-type outlet and inlet valves in order to guide the operator in closing the valve so unpasteurized milk is not permitted to enter the outlet line or holder respectively.
 - (5) Outlet valves must be designed to prevent the accumulation of unpasteurized milk in the valve passages when the valve is in closed position.
 - (6) Inlet pipelines and outlets from vat pasteurizers must be equipped with leak protector valves unless piping is so arranged that only one vat can be connected to the inlet line at a time, and this one

vat must be disconnected during holding and emptying periods.

- (7) Inlet and outlet connections other than through close-coupled valves may not enter or leave the pasteurizer below the level of milk therein.
- (8) When the inlet line enters the holder above the milk level, the inlet line must be provided with an automatic air relief or vent located at the valve or elsewhere and designed to function in every closed position.
- (9) All leak detector valves must be installed in the proper position to ensure the function of the leak diverting device.
- (10) All outlet valves must be kept fully closed during filling, heating, and holding periods. All inlet valves must be closed during holding and emptying periods.

2. High temperature short time continuous flow pasteurization.

- a. Indicating thermometers and recorder/controller instruments must comply with state standards.
- b. Automatic milk flow controls. Each high temperature short time must be equipped with a flow-diversion device which automatically causes the diversion of milk in response to a sublegal pasteurization temperature. This device must comply with all of the following specifications:
 - (1) Forward flow of subtemperature milk under any circumstance is prohibited.
 - (2) When a packing gland is used it must be impossible to tighten the stem packing nut to such an extent so as to prevent the valve from assuming a fully diverted position.
 - (3) A leak escape must be installed on the forward flow side of the valve seat or when back pressure is exerted on the valve seat. The leak escape should lie between the two valve seats or between two portions of the same seat. All leakage must be discharged through a line separate from the diversion device. If discharged to a constant level on the tank, a sight glass must be installed on the line.
 - (4) The closure of the forward flow seat must be tight so that leakage past it will not exceed the capacity of the leak escape device.

- (5) The length of the connecting rod may not be adjustable.
- (6) Failure of the devices primary motivating power must automatically divert the flow of milk.
- (7) The flow-diversion device must be located downstream from the holder and the flow control sensor must be located in the milk line not more than eighteen inches [457.20 millimeters] upstream from the flow control device.
- (8) The pipeline from the flow-diversion device must be self-draining and free of restriction unless so designed that stoppage of the diversion line cannot occur.
- (9) When used, the pipeline from the leak detector port must meet the criteria provided in paragraph 8.

c. Holding tubes must be so designed:

- (1) To hold every particle of milk and milk products for at least the legal time.
- (2) To assure simultaneous temperature difference can be assumed one degree Fahrenheit [0.55 degrees Celsius] in holders of seven inches [177.8 millimeters] or smaller.
- (3) To assure that short circuiting a portion of the holder is not possible.
- (4) To have an upward slope in the direction of flow not less than twenty-five inches per foot [6.35 millimeters per 304.8 millimeters].
- (5) And be provided with supports to maintain all parts of holding tubes in a fixed position.
- (6) To assure that no portion between the inlet and the flow control temperature sensor is heated.

d. Indicating and recording thermometers.

- (1) Indicating and recording thermometers must be located as close as possible to the temperature sensor of the recorder controller.
- (2) The temperature of the recorded controller must be checked daily against the indicator by the plant operator and readings recorded on the chart. The

recorder controller must read no higher than the indicating thermometer.

e. Flow-promoting devices.

- (1) Equipment which may produce flow through the holder must be upstream from the holder unless the flow-promoting devices have a means provided to eliminate negative pressure.
- (2) Vacuum equipment located downstream from the holder must have an effective vacuum breaker plus automatic means of preventing negative pressure.
- (3) The speed of pumps or other flow-promoting devices governing the rate of flow through the holder must be controlled to hold every particle of milk to comply with the legal definition of pasteurization. They must be sealed after being checked by the dairy commissioner and if the seal is broken, the dairy department must be notified immediately. The metering or timing pump must be of the positive displacement type.
- (4) The holding time tests must be taken when all equipment and devices are operated and adjusted to provide for maximum flow. It must be tested in both forward and divert flow initially and semiannually thereafter by the dairy department, and also when the seal of the steep setting has been broken.

3. Milk to milk regenerative heating.

- a. Pasteurizers employing milk to milk regenerative heating with both sides closed to the atmosphere must comply with the following specifications:
 - (1) Regenerators must be constructed, installed, and operated so that the pasteurized product in the regenerator will automatically be under greater pressure than the raw product.
 - (2) Pasteurized product between regenerator and the nearest point downstream open to the atmosphere must rise to a vertical elevation twelve inches [304.80 millimeters] above the highest raw milk downstream from the constant level tank and must be open to the atmosphere at this or a higher elevation.
 - (3) The overflow of the top rim of the balance tank must be lower than the lowest level of milk in the regenerator.

- (4) No pump flow-promoting devices which can effect proper pressure relationships within the regenerator may be located between the product outlet from the regenerator and the nearest point downstream open to the atmosphere.
 - (5) No pump may be located between the raw milk inlet to the regenerator and the raw milk supply tank unless designed and installed to operate only when milk is flowing through the pasteurized side and the pressure on the pasteurized side is greater than the pump's maximum pressure. To accomplish this, the booster pump must be wired so operation is impossible unless:
 - (a) The metering pump is operating.
 - (b) The flow-diversion device is in the forward flow position.
 - (c) The pasteurized product pressure exceeds maximum pressure developed by the booster pump by one pound per square inch [6.87 kilopascals]. Pressure gauges must be installed at the inlet and outlet of the regenerator or in lieu of regeneration outlet-cooler outlet. These will be checked by the regulatory agency.
 - (6) The motor casing and impeller of the booster pump must be identified and such records maintained.
 - (7) All raw milk in the regenerator must drain back to the balance tank when raw pumps are shut down and raw milk outlet from the regenerator is disconnected.
 - (8) Vacuum equipment located downstream from the flow-diversion device must be provided to prevent the lowering of pasteurized product level in the regenerator during periods of diverted flow or shut down. An effective vacuum breaker plus automatic means of preventing a negative pressure must be installed in the line between the vacuum chamber and the pasteurized product inlet to the regenerator.
- b. Milk to water to milk regenerative heating.
- (1) Milk to water to milk regenerative heating must be designed, installed, and operated so that the heat transfer medium side of the regenerator in the raw milk section is under greater pressure than the raw milk side at all times.
 - (2) The heat transfer water must be safe and in a covered tank open to the atmosphere at an elevation twelve

inches [304.80 millimeters] higher than any raw milk level downstream from the balance tank. The heat transfer water between its regenerator outlet and the nearest downstream point must be open to the atmosphere and must rise to a vertical elevation of at least twelve inches [304.80 millimeters] above any raw milk.

- (3) The heat transfer water circuit must be full of water at the beginning of the run and all loss of water from the circuit must be automatically and immediately replenished whenever raw milk is present in the regenerator.
- (4) The overflow of the top rim of the balance tank must be lower than the lowest level of milk in the regenerator.
- (5) All raw milk must drain freely back to the upstream supply tank when the raw milk pumps are shut down and the raw milk outlet from the regenerator is disconnected.
- (6) No pump may be located between the raw milk inlet to the raw milk supply tank unless designed and installed to operate when water is flowing through the heat transfer section of the regenerator, and when the pressure of the heat-transfer water is higher than the pressure of the raw milk. This may be accomplished by wiring the booster pump so that it cannot operate unless the heat transfer water pump is operating, and the heat transfer water pressure exceeds raw milk pressure in the regenerator by at least one pound per square inch [6.87 kilopascals]. Pressure gauges must be installed at the raw milk outlet and the heat transfer water outlet of the regenerator. The accuracy of these pressure gauges must be checked by the dairy commissioner upon installation, quarterly, and after repair.

4. Temperature recording charts, equipment tests, and examination.

- a. All temperature recording charts must be preserved at the plant for a period of three months.
- b. The use of temperature recording charts may not exceed the time limit for which they are designed.
- c. The following information must be entered on the charts as applicable.
 - (1) Batch pasteurizers.

- (a) Date.
 - (b) Number or location of recorder when more than one is used.
 - (c) Extent of holding period including filling and emptying times.
 - (d) Reading of airspace thermometer.
 - (e) Reading of indicating thermometer.
 - (f) Quarterly, the initials of the dairy commissioner opposite the required readings of the indicating thermometer and airspace thermometer.
 - (g) Quarterly, the time accuracy of the recorder as determined by the dairy commissioner.
 - (h) Amount and name of pasteurized milk and milk products represented by each batch or run on the chart.
 - (i) Record of unusual occurrences.
 - (j) Signatures or initials of operator.
 - (k) Name of milk plant.
- (2) High temperature short time charts must have all the information as specified in subdivision c of subsection 4, except subparagraphs c, d, and f; a record of the time during which the flow-diversion device is in the forward flow position; and the cut-in and cut-out milk temperature recorded daily by the operator at the beginning of the run and initialed by the dairy department quarterly.

d. The dairy commissioner shall conduct equipment tests on instruments, upon installation and once every three months thereafter, and when repairs or alterations are made. The salt test must be conducted once every six months.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-17. Cooling of milk.

1. Raw milk product must be maintained at forty-five degrees Fahrenheit [7.22 degrees Celsius].

2. Pasteurized milk and milk products, except those to be cultured, must be cooled immediately in approved equipment to forty-five degrees Fahrenheit [7.22 degrees Celsius] or less, prior to packaging.
3. Storage of pasteurized milk and milk products must be forty-five degrees Fahrenheit [7.22 degrees Celsius] or less.
4. In delivery vehicles, the temperature of the milk and milk products may not exceed fifty degrees Fahrenheit [10 degrees Celsius].
5. Each refrigerator room in which milk or milk products are stored must be equipped with an indicating thermometer located in the warmest zone of the room.
6. Each storage tank must be equipped with an indicating thermometer the sensor of which must be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent of its calibrated capacity.
7. Surface coolers must meet all of the following specifications:
 - a. The sections of open surface coolers must leave a gap of at least twenty-five hundredths inch [6.35 millimeters] between the header sections for ease of cleaning.
 - b. Where header ends are not completely enclosed, condensation or leakage from headers must be prevented from entering the milk and milk products.
 - c. The cooler must be located to prevent drips from entering the milk or milk products.
8. Recirculated cold water used in coolers and exchangers must be a safe source protected from contamination, tested semiannually, and must comply with bacteriological standards. If systems become contaminated, they must be properly treated and retested.
9. Freezing point depressants, when used, must be nontoxic.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-18. Bottling and packaging.

1. All milk and milk products must be bottled and packaged at the plant where final pasteurization is performed without undue delay after pasteurization.

2. All bottling or packaging must be done on approved mechanical equipment. This does not exclude manually operated machinery but does exclude methods in which the bottling and capping devices are not integral in one system.
3. Bottling or packaging machines are designed to minimize needs for adjustment during operation.
4. Bottling or packaging machine supply tanks and bowls must have covers which are constructed to prevent any contamination. All covers must be in place during operation.
5. A drip deflector designed and adjusted to divert condensation must be installed on each filler valve.
6. Container in-feed conveyors to automatic bottling or packaging machines must have overhead shields to protect the bottles or packages from contamination.
7. Container fabricating materials must be handled in a sanitary manner and protected against undue exposure during the package assembly operation.
8. Floats on machines must be designed to be adjustable without removing the cover.
9. The filler pipe of all bottling and packaging machines must have an apron or other approved device as close to the filler bowl as possible.
10. Filling cylinders on packaging machine must be protected from contamination by use of overhead shields.
11. Lubricants applied to milk contact surfaces must be nontoxic, sterile, and applied sparingly and in a sanitary manner.
12. Cottage cheese, dry curd cottage cheese, and lowfat cottage cheese may be transported in sealed containers in a protected sanitary manner from one plant to another for creaming or packaging.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-19. Capping.

1. Capping or closing must be performed in a sanitary manner by approved mechanical equipment. This may not exclude manually operated equipment. If suitable equipment is not available for capping cottage cheese, dry curd cottage cheese, and

lowfat cottage cheese, other methods which eliminate possible contamination may be approved by the dairy commissioner.

2. Hand capping will not be allowed unless containers are three gallons [11.36 liters] or more and the method used eliminates all possibility of contamination.
3. Need for adjustment of equipment during operation must be kept at a minimum.
4. Imperfectly capped and closed products must be emptied into approved sanitary containers immediately, protected from contamination, maintained at forty-five degrees Fahrenheit [7.22 degrees Celsius] or less, and repasteurized, or in lieu of repasteurization, discarded.
5. All caps and closures must be designed and applied so as to protect the pouring lip to at least its largest diameter. Removal of caps cannot be made without detection. Closures for cottage cheese, dry curd cottage cheese, and lowfat cottage cheese containers must extend over the top edges of the container.
6. Caps and closures must be handled in a sanitary manner. The first cap, the first lap from each roll of cap or cover stock, and the first sheet of parchment or cover paper must be discarded. This does not apply to cottage cheese, dry curd cottage cheese, and lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package or wrapped so as to protect the closures.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-20. Personnel cleanliness.

1. Hands must be washed before commencing plant functions and whenever soiled or contaminated.
2. All persons engaged in processing, pasteurization, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils must wear clean outer garments, caps (paper caps, hard hats, or hair nets), and beard nets (males).
3. Tobacco may not be used by any person while engaged in the processing of milk or milk products.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-21. Vehicles. All vehicles used for transportation of pasteurized milk and milk products must be constructed and operated so that the milk and milk products are maintained at forty-five degrees Fahrenheit [7.22 degrees Celsius] or less and are protected from sun, from freezing, and from contamination. Vehicles must be kept clean. No contaminating substances may be transported in a vehicle that hauls milk and milk products. Vehicles must have fully enclosed bodies with well-fitted solid doors.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

7-03.1-14-22. Surroundings. Surroundings must be neat and clean, free of pooled water, harborage, and fly and rodent breeding areas. Only approved insecticides and rodenticides may be used. Driveways, lanes, and areas serving milk plant vehicular traffic must be graded, drained, and free from pools of standing water.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-36

**CHAPTER 7-03.1-15
TRANSPORTATION OF MILK AND CREAM FOR MANUFACTURING,
PROCESSING, OR BOTTLING PURPOSES**

Section

7-03.1-15-01	Licensing
7-03.1-15-02	Equipment and Vehicles
7-03.1-15-03	Raw Milk Pickup
7-03.1-15-04	Pup Trailers
7-03.1-15-05	Wash Records
7-03.1-15-06	Topping Off

7-03.1-15-01. Licensing. All persons involved in the transportation of milk and cream for manufacturing purposes must be licensed as specified in North Dakota Century Code section 4-30-38.1, with the exception of producer haulers.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-12, 4-30-38.1

7-03.1-15-02. Equipment and vehicles. The maximum amount of time between pickup of milk on the farm is four days. All equipment used in the transport of raw milk or cream must conform to 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, or

be approved by the dairy commissioner. Equipment not meeting 3A sanitary standards and not having the dairy commissioner's approval must be sealed or tagged by the dairy commissioner. Use of sealed or tagged equipment will result in the suspension of the hauler's license. Vehicles used for transporting raw milk may not be used for transporting other products, unless approved by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-38

7-03.1-15-03. Raw milk pickup.

1. Raw milk picked up on the farm must be stored in containers meeting all the following requirements:
 - a. Compliance with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, or approved by the dairy commissioner.
 - b. Ability to agitate to obtain a universal sample.
 - c. Ability to hold milk at a temperature between thirty-two to forty-five degrees Fahrenheit [0 to 7.22 degrees Celsius].
2. Only raw milk stored on the farm in bulk tanks approved by the dairy commissioner may be picked up. It is a violation of this section to add milk stored in containers not complying with this section to milk stored in a container meeting the requirements of this section.
3. Filter bowls or open bowl strainers with fiber filters must comply with 3A sanitary standards as defined in North Dakota Century Code section 4-30-01. Only approved in-line filtering devices may be used when transferring milk from a farm bulk tank to a farm bulk truck. These devices must be stored in a sanitary manner.
4. During transfer of all milk or milk products from farm bulk trucks or tankers, a filter is required for any air inlet vent when transfer occurs outside or in an area not completely enclosed.
5. Transfer of all milk and milk products between trucks or between truck and tankers must be made from valve to valve with adequate filter protection for air inlet vent.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-38

7-03.1-15-04. Pup trailers. When pup trailers are used in hauling milk and milk products, the connecting pipeline between the main tanker and pup trailer must be kept free of milk or milk products during transport. Any milk retained in the connecting pipeline must be disposed of and not transferred to plant storage silos or tanks. These connecting pipelines or hoses must be cleaned and sanitized between each use.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-38

7-03.1-15-05. Wash records.

1. All farm bulk trucks used for transporting raw milk from the farm to the plant shall maintain a record of washing and sanitizing at the end of each day's use. This record may consist of a mechanical recording chart, a wash log, or any other approved method which contains the following information:

- a. Truck identification.
- b. Washer identification.
- c. Date.
- d. Time.
- e. Name and location of washing facility.

All items such as valves and milk pumps which cannot be cleaned in place must be manually cleaned and sanitized at the end of each day's use.

2. All tankers and farm bulk trucks washed and sanitized outside the state of North Dakota will require a seal on the outlet valve and wash tag containing the following information:

- a. Truck identification.
- b. Location of wash station.
- c. Date and time of washing.
- d. Name of individual responsible for washing and sanitizing.

All milk transported in tankers or farm bulk trucks which are washed out of state and do not have the required seal and wash tag must be diverted to nongrade A uses.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-38

7-03.1-15-06. Topping off. Milk haulers are responsible for always completely emptying a farm bulk tank at every pickup. If this is not possible, the milk remaining in the farm bulk tank must be picked up before the next milking. Failure to completely empty the farm bulk tank prior to next milking is defined as "topping off". It is a violation of this section to top off any farm bulk tank.

History: Effective August 1, 1986.
General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-38

CHAPTER 7-03.1-16 MILK HAULERS LICENSING

Section	
7-03.1-16-01	License Requirements
7-03.1-16-02	Training
7-03.1-16-03	Violations

7-03.1-16-01. License requirements. All persons other than milk producers or dairy plant employees engaging in over-the-road transport of milk or milk products, but not required to sample, must be licensed as milk haulers. All private owners of over-the-road tankers and farm bulk trucks must be licensed as milk haulers. All the following items must be complied with in order to obtain a license:

1. The vehicles hauling milk must be properly identified with the owner's name, address, and identification number.
2. The truck and tank must comply with 3A sanitary standards, as defined in North Dakota Century Code section 4-30-01, for unrefrigerated tanks storing milk and milk products.
3. Application must be made to the dairy commissioner for a license. The license must be renewed annually.

History: Effective August 1, 1986.
General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-38.1

7-03.1-16-02. Training. The milk hauler is responsible to provide for training of new employees, samplers, and haulers, and for scheduling with the dairy department annual training sessions.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-38.1

7-03.1-16-03. Violations. The milk hauler is responsible for willful acts of any employee who violates the requirements of chapters 7-03.1-02, 7-03.1-15, and 7-03.1-16. For violations of the requirements for wash records, topping off, or picking up raw milk from the farm in unapproved containers, the dairy commissioner shall either suspend the license or proceed pursuant to the provisions of North Dakota Century Code section 4-30-53.

History: Effective August 1, 1986.
General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-38.1

CHAPTER 7-03.1-17 TRANSPORTATION OF PROCESSED AND MANUFACTURED PRODUCTS

Section	
7-03.1-17-01	License - Violations
7-03.1-17-02	Vehicle Requirements

7-03.1-17-01. License - Violations. All parties who transport processed and manufactured dairy products from the processing plant for retail sale or sale directly to the consumer must be licensed in compliance with North Dakota Century Code section 4-30-02. It is a violation of this chapter to transport dairy products which have exceeded their code date for retail sale from the processing plant.

History: Effective August 1, 1986.
General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1
Law Implemented: NDCC 4-30-02, 4-30-39, 4-30-53

7-03.1-17-02. Vehicle requirements. All vehicles used in the transport of dairy products covered under this section must comply with all the requirements listed below:

1. A temperature of forty-five degrees Fahrenheit [7.22 degrees Celsius] or lower must be maintained in the storage area of the delivery vehicle.
2. All milk and milk products must be maintained at forty-five degrees Fahrenheit [7.22 degrees Celsius] or lower. Failure to maintain milk and milk products in the temperature range of thirty-two to forty-five degrees Fahrenheit [0 to 7.22 degrees Celsius] will require use of a refrigerated storage

compartment. Ultrapasteurized and aseptically processed dairy products are exempt from this requirement.

3. The interior of the storage area must be cleaned daily and free from insects and rodents.
4. An approved thermometer must be mounted in the storage area of all vehicles used to transport processed and manufactured dairy products.
5. All newly licensed distributors must have an inspection of their facilities and equipment prior to licensing. Application for a distributor license must be made with the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-39

CHAPTER 7-03.1-18 BRANDING CANS, KEGS, BARRELS, AND RECEPTACLES

Section

7-03.1-18-01	Registration
7-03.1-18-02	Hearing - Violation
7-03.1-18-03	Return

7-03.1-18-01. Registration. Any person in possession of any container, cabinet, or other dairy equipment which is marked with a brand registered with the dairy commissioner must either be the recorded owner of the brand or must have written documentation from the owner of the brand which permits use of the item. The written documentation must be made available to the dairy commissioner upon request. All containers, cabinets, or other dairy equipment, marked with a registered brand may require a deposit as security for the use and return of the branded item. This does not constitute a sale of the branded item.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-44

7-03.1-18-02. Hearing - Violation. Upon receipt of a written complaint charging noncompliance with North Dakota Century Code section 4-30-44, the dairy commissioner shall conduct a hearing pursuant to North Dakota Century Code chapter 28-32 to determine the rightful owner of the branded containers, cabinets, or other dairy equipment.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-44, 4-30-53

7-03.1-18-03. Return.

1. Any person that finds, receives, or otherwise comes into possession of any container, cabinet, or other dairy equipment without purchase which is marked with a brand which is registered with the dairy commissioner, shall within seven days return it to the owner or the owner's agent. If identification of the owner or agent is in doubt, the person shall within seven days notify the dairy commissioner in writing about finding, receiving, or otherwise coming into possession of the container, cabinet, or other dairy equipment, and particularly describe in the notice the trademark or brand which is on the container, cabinet, or other dairy equipment.
2. Any distributor in possession of a milk case having another distributor's registration shall notify the registered owner or agent for pickup upon receipt of payment of any case deposit which the distributor in possession may have paid for the case.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-44

**CHAPTER 7-03.1-19
OFFICIAL BUTTERFAT TEST FEE**

Section

7-03.1-19-01

Official Butterfat Test Fee

7-03.1-19-01. Official butterfat test fee. A fee of ten dollars for each party involved in the dispute, namely the seller and buyer, must be charged for an "Official Butterfat Test." The fee must be sent to the office of the dairy commissioner along with the sample in question. The office of dairy commissioner must be interpreted to mean "the office of dairy commissioner or the commissioner's designated representative." The official testing laboratory for results of the official butterfat test must be designated by the dairy commissioner.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-47

**CHAPTER 7-03.1-20
LABELING OF MILK AND MILK PRODUCTS FOR RETAIL SALES**

Section

7-03.1-20-01	Federal Requirements
7-03.1-20-02	Cheese Labeling
7-03.1-20-03	Sodium Labeling
7-03.1-20-04	Frozen Desserts

7-03.1-20-01. Federal requirements. All milk and milk products must comply with the labeling and nomenclature requirements of title 21, Code of Federal Regulations, parts 131, 133, and 135 inclusive, except where state law takes precedence.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-45

7-03.1-20-02. Cheese labeling.

1. Bulk cheese must be legibly marked with:
 - a. The name of the product.
 - b. Code or date, or both, of manufacture.
 - c. Vat number.
 - d. Officially designated code number or name and address of manufacturer.
 - e. Statement as to whether the product is pasteurized or heat treated.
 - f. Other required information as listed in title 21, Code of Federal Regulations, part 133.
2. Each consumer sized container must be marked with:
 - a. Name and address of the manufacturer.
 - b. Packer or distributor.
 - c. Net weight of the contents.
 - d. Name of the product.
 - e. Vat number.
 - f. Date of manufacture.

- g. Date of packing.
 - h. Other required information as listed in title 21, Code of Federal Regulations, part 133.
3. In lieu of the requirements of subsections 1 and 2 where labeling of consumer sized packages is not practical, a record of dates, names, vat numbers, etcetera of the original bulk cheese must be kept on file at the particular establishment for a period of one year and made available to the dairy commissioner upon request.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-45

7-03.1-20-03. Sodium labeling.

- 1. As used in this section:
 - a. Salt refers to the sodium chloride, but is not synonymous with sodium.
 - b. Sodium free may be used on the label and in labeling of foods that contain less than five milligrams of sodium per serving.
 - c. Very low sodium may be used to designate foods containing thirty-five milligrams or less of sodium per serving.
 - d. Low sodium may be used to designate foods containing one hundred forty milligrams or less of sodium per serving.
 - e. Reduced sodium may be applied to foods that have been formulated to serve as and are represented as direct replacements for foods containing at least four times the sodium content (i.e., reflect at least seventy-five percent reduction).
 - f. The terms "unsalted," "no salt added," and "without salt added" may only be used in the following cases:
 - (1) No salt is added during processing.
 - (2) The food it resembles or for which it substitutes normally is processed without salt.
 - (3) Sodium labeling is provided.

The label shall give information comparing the food's sodium content per serving with that of the food it replaces if the term "reduced" sodium is used.

2. The declaration of nutrition information must specify "sodium content" or "sodium" as milligrams per specified serving of food, expressed to the nearest multiple of five milligrams for foods containing from five to one hundred forty milligrams or ten milligrams for foods containing greater than one hundred forty milligrams per serving, and located on the label immediately following the statement of fat content (and fatty acid or cholesterol, or both, if stated).
3. If nutrition labeling is not used, a statement of the number of milligrams of sodium per serving, as "contains _____ milligrams sodium per (size) serving" may be provided on the principle or information panel. Sodium content must be expressed as zero (0) when a serving contains less than five milligrams.
4. A food will be considered misbranded if the sodium content is greater than twenty percent in excess of the label - declared sodium label. Reasonable deficiencies of calories, fat, or sodium are acceptable within current good manufacturing practice.
5. Potassium content information may be voluntarily included on the nutritional labeling format.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-45

7-03.1-20-04. Frozen desserts. All frozen dessert labels must include:

1. Name of product.
2. Name of plant which processed product.
3. Address of processor.
4. Size or volume of container.
5. Whether product is naturally or artificially flavored.
6. List of ingredients in descending order.
7. Other pertinent information as required by title 21, Code of Federal Regulations, part 135.

History: Effective August 1, 1986.

General Authority: NDCC 4-29-03, 4-29-04, 4-30-55.1

Law Implemented: NDCC 4-30-45

TITLE 10
Attorney General

SEPTEMBER 1986

10-03-03-02. Qualifications as an apprentice security officer. To qualify for registration as an apprentice private security officer, a person:

1. Must complete a minimum of sixteen hours of classroom instruction, relating to the provision of private security services before being uniformed and assigned to duty. This instruction must include the apprentice security officer training curricula (contained in appendix "A") plus first aid training as required by the private investigative security board, and other instruction as determined by the employer for the particular assignment intended. However, a person may be employed by a private security agency for up to thirty days within any calendar year without having received the training required by this subsection, provided that the person is directly supervised onsite by a security officer or commissioned security officer employed by the private security agency.
2. Must receive a minimum of sixteen hours of field training, under the supervision of a security officer who has a minimum of two thousand hours of active service in that grade or equivalent combination of training and experience as defined in section 10-03-03-07, or under the supervision of a commissioned security officer, before being allowed to perform duties without direct supervision.

History: Effective July 1, 1985; amended effective September 1, 1986.

General Authority: NDCC 43-30-04

Law Implemented: NDCC 43-30-04

10-03-03-03. Qualifications for security officer. To qualify for registration as a security officer, an individual:

1. After one thousand hours, but before two thousand hours, as an active apprentice security officer, must an individual may make application with the attorney general for registration as a private security officer. The individual must then qualify to become a security officer in order to remain qualified to perform private security services in this state.
2. Must complete an additional thirty-two hours of classroom instruction as required by the private investigative security board. This instruction must include the security officer training curriculum (contained in appendix "B") required by the private investigative security board, and other instruction as determined by the employer for the particular assignment intended.

History: Effective July 1, 1985; amended effective September 1, 1986.

General Authority: NDCC 43-30-04

Law Implemented: NDCC 43-30-04

10-03-03-05. Qualifications for armed security personnel. It is unlawful for any person while providing private security services to carry a firearm, unless the individual carrying the firearm:

1. Has achieved at least the rank of security officer as defined in section 10-03-03-03;
2. Has completed the same requirements for firearms training as is required for North Dakota peace officers; and
3. Has been issued the armed private security certificate required by subsection 5 of North Dakota Century Code section 43-30-16. Armed private security certificates expire on September thirtieth of each year.

History: Effective July 1, 1985; amended effective September 1, 1986.

General Authority: NDCC 43-30-04

Law Implemented: NDCC 43-30-04

10-03-03-08. Licensing of persons providing private security. Any person providing private security services must obtain a private security license from the attorney general unless the person is registered as an employee of a licensed private security agency. To be eligible for this license, the person must be registered as a commissioned security officer, either by registration or by the equivalency provisions as defined in section 10-03-03-07, and have passed an examination conducted by or under the supervision of the attorney general.

History: Effective July 1, 1985; amended effective September 1, 1986.

General Authority: NDCC 43-30-04

Law Implemented: NDCC 43-30-05, 43-30-06

10-03-03-09. Qualifications and licensing for private security agency. Any person hiring another person to perform private security services must obtain a private security agency license. Any individual who applies for a private security agency license must themselves be licensed to perform private security services in this state and have at least two consecutive years of experience as a person providing private security services in any jurisdiction of the United States or have met the equivalency requirements of section 10-03-03-07. A corporation or partnership which applies for a private security agency license must have at least one member of the partnership or corporate officers of the corporation who is **registered in this state as a commissioned security officer and who has performed private security services for at least two consecutive years.** licensed to perform private security services in this state and who has at least two consecutive years of experience as a person providing private security services in any jurisdiction of the United States or has met the equivalency requirements of section 10-03-03-07.

History: Effective July 1, 1985; amended effective September 1, 1986.

General Authority: NDCC 43-30-04

Law Implemented: NDCC 43-30-04

STAFF COMMENT: Chapter 10-12-01 contains all new material but is not underscored so as to improve readability.

ARTICLE 10-12

CONCEALED WEAPONS

Chapter
10-12-01 Concealed Weapons Permit

CHAPTER 10-12-01 CONCEALED WEAPONS PERMIT

Section	
10-12-01-01	Incomplete Application
10-12-01-02	Permits for Multiple Types of Weapons
10-12-01-03	Nonresident Applicants
10-12-01-04	Written Test
10-12-01-05	Proficiency Test
10-12-01-06	Lost or Destroyed Permits
10-12-01-07	Revocation or Suspension of a Concealed Weapons Permit

10-12-01-08	Denial of a Concealed Weapons Permit
10-12-01-09	Residence Change
10-12-01-10	Appeals
10-12-01-11	Applicability of Requirements

10-12-01-01. Incomplete application. All applications for a concealed weapons permit must be made on a form approved by the chief agent of the bureau of criminal investigation. All applications received by the chief agent of the bureau of criminal investigation must be completed before they will be considered for approval and processing. To be considered complete, an application must:

1. Have all the information blanks on the front of the application answered, either with the information requested or with an N/A for nonapplicable where appropriate.
2. Have the test block section on the reverse side of the application filled in by the test administrator. The test administrator must indicate whether the written and proficiency tests have been passed and must include that administrator's signature.
3. Have the signed approval of the local county sheriff.
4. Have the signed approval of the local chief of police, if there is one.
5. Have one fingerprint card containing the classifiable fingerprints of the applicant attached.
6. Have two driver's license-style color photographs attached.

All incomplete applications received by the chief agent of the bureau of criminal investigation will be returned to the applicant for completion.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-02. Permits for multiple types of weapons. If an individual wishes a concealed weapons permit for several different weapons types, i.e., firearm and knife, stun gun and knife, etc., only one written test need be taken and passed. However, the applicant must pass a proficiency test for each weapon type for which a proficiency test is required. The test administrator may charge for each proficiency test, as long as the total charge does not exceed fifty dollars.

If the applicant wishes to obtain a concealed weapons permit for additional weapons types after receiving the initial permit, then a new application with the word "amended" printed on the top must be

completed. The only blank on the application that would not need to be completed is the blank indicating that the written test has been passed. The test administrator may charge a fee for the proficiency test on these additional weapons types as long as that fee does not exceed fifty dollars.

History: Effective September 1, 1986.
General Authority: NDCC 62.1-04-03
Law Implemented: NDCC 62.1-04-03

10-12-01-03. Nonresident applicants. Residents of the United States who are not residents of North Dakota may obtain a North Dakota concealed weapons permit. To obtain a permit, the individual must complete the same application process and meet the same criteria as a North Dakota resident.

History: Effective September 1, 1986.
General Authority: NDCC 62.1-04-03
Law Implemented: NDCC 62.1-04-03

10-12-01-04. Written test. The written test must be an open-book test approved by the attorney general. The test must consist of ten questions.

History: Effective September 1, 1986.
General Authority: NDCC 62.1-04-03
Law Implemented: NDCC 62.1-04-03

10-12-01-05. Proficiency test. The attorney general shall set forth the criteria for the proficiency tests.

For firearms, it must be as follows:

1. **Target.** Must be a humanoid, silhouette target of either the duelatron or the B-27 type.
2. **Range.** Seven yards (twenty-one feet [6.40 meters]) .
3. **Time.** Five minutes.
4. **Number of rounds.** Ten. No more than six rounds may be loaded at any time. The individual must safely reload during the firing sequence.
5. **Weapon.** Any safe weapon with any type of ammunition suitable for that weapon may be used.
6. **Starting position.** The weapon must be loaded and holstered after arrival to the line and under the direction and observation of the test administrator. Upon command, the

weapon should be drawn and fired. If no holster is to be used, then any safe carrying method may be used.

7. **Scoring.** All hits on the silhouette count one point. Seven points are needed to pass.
8. **Position.** Any standing position may be used, i.e., one-handed or two-handed, "weaver" stance, "crouch," etc.
9. **Passing.** In order to pass, the individual must:
 - a. Score a minimum of seven points; and
 - b. Be able to load, unload, carry, and fire the weapon safely.

Only this course of fire may be used.

For other weapons, it must be designated by the attorney general on an individual weapon type basis. The emphasis on this testing must be testing the applicant for familiarity with the weapon and to demonstrate safety in the handling of that weapon type.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-06. Lost or destroyed permits. If a permit holder loses his or her permit or it is destroyed, a replacement may be obtained. In order to obtain a new permit, the applicant must send a letter to the chief agent of the bureau of criminal investigation indicating the applicant's name, address, and date of birth. In addition, the letter must state the reason the applicant needs a replacement permit. In addition, the applicant must also attach one driver's license-style photograph to the letter.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-07. Revocation or suspension of a concealed weapons permit. The chief agent of the bureau of criminal investigation may revoke or suspend a concealed weapons permit for the following reasons:

1. The permit holder has become one of the persons listed in North Dakota Century Code section 62.1-02-01; or
2. Upon the written recommendation of any law enforcement officer or upon information received from any other source that would indicate to the chief agent of the bureau of criminal

investigation that there exists a valid reason to revoke or suspend such permit. Examples of those valid reasons are as follows:

- a. A criminal violation occurred while the permitholder was in the possession of a concealed weapon.
- b. A conviction of any weapons law or this chapter has occurred.
- c. The applicant made a material false statement on the application form for the concealed weapons permit.
- d. Any other good and valid reason that has a direct bearing on the individual's fitness to carry and possess a concealed weapon.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-08. Denial of a concealed weapons permit. The chief agent of the bureau of criminal investigation may deny a concealed weapons permit for any of the following reasons:

1. The applicant is prohibited by North Dakota Century Code section 62.1-02-01 from possessing any weapon.
2. The applicant has failed to state a valid reason to possess a concealed weapon.
3. The applicant has not filed a completed application as required in section 10-12-01-01.
4. The applicant made a material false statement on the application for a concealed weapons permit.
5. For any other good and valid reasons that has a direct bearing on the individual's fitness to carry and possess a concealed weapon.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-09. Residence change. All holders of a concealed weapons permit must notify the chief agent of the bureau of criminal investigation within thirty days of their moving to an address different than what is listed on their permit of that change of address. That notification must be in writing and must contain at a minimum the applicant's name, former address, permit number, and new address. The

new address must include house number or apartment number, street name, city, zip code, and county.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-10. Appeals. All appeals of decisions of the chief agent of the bureau of criminal investigation must be made pursuant to and in accord with North Dakota Century Code chapter 28-32.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

10-12-01-11. Applicability of requirements. All three-year permits are issued pursuant to and subject to this chapter and all North Dakota weapons law restrictions.

History: Effective September 1, 1986.

General Authority: NDCC 62.1-04-03

Law Implemented: NDCC 62.1-04-03

TITLE 11

Audiology and Speech-Language Pathology, Board of Examiners on

AUGUST 1986

11-02-01-06. Continuing education. To renew a license a person must present proof of having attended at least six clock hours of continuing education approved by the board.

Continuing education for licensure renewal must be completed in the calendar year prior to the year for which licensure is sought. Under extraordinary circumstances the board may consider a request for continuing education hours accrued in the same calendar year.

Such continuing education courses must be related to or increase the professional competence of the attendee. This determination will be made by the board through approval of requested courses. If any licensee allows their license to lapse for a period of more than one year, the licensee is required to submit proof of attendance of at least six clock hours of continuing education for each year that the license has lapsed up to a total of eighteen continuing education hours.

Continued practice in violation of the continuing education requirements as outlined in this section may subject a licensee to disciplinary action as outlined in North Dakota Century Code section 43-37-13.

History: Amended effective May 1, 1984; August 1, 1986.

General Authority: NDCC 43-37-06

Law Implemented: NDCC 43-37-06

TITLE 13

Banking and Financial Institutions, Department of

SEPTEMBER 1986

STAFF COMMENT: Chapter 13-02-09 contains all new material but is not underscored so as to improve readability.

CHAPTER 13-02-09
LOAN LIMITATION TO ONE BORROWER OR CONCERN

Section	
13-02-09-01	Purpose
13-02-09-02	Definitions
13-02-09-03	Liabilities of a Borrower
13-02-09-04	Loans to Corporations and Principals
13-02-09-05	Loans to Members of a Partnership or Association

13-02-09-01. Purpose. This chapter is intended to safeguard the depositors of state banking associations by requiring the diversification of loan portfolios and repayment sources.

History: Effective September 1, 1986.

General Authority: NDCC 6-01-04

Law Implemented: NDCC 6-03-59

13-02-09-02. Definitions. In determining the total direct, indirect, or contingent liability of a borrower for purposes of North Dakota Century Code section 6-03-59, the following definitions apply:

1. "Contingent liability" includes a potential economic obligation of an enterprise if it is (a) probable that a liability will be incurred and (b) the amount of the liability can be reasonably estimated.

2. "Direct liability" means all obligations of an enterprise for which it has primary responsibility for repayment.
3. "Indirect liability" includes a potential economic obligation of an enterprise if it is (a) probable that a liability will be incurred and (b) the amount of the liability can be reasonably estimated.
4. "Parent corporation" means a corporation which owns or controls one or more subsidiaries.
5. "Probable" means that a future event or events that would cause a contingency to become a liability are likely to occur.
6. "Subsidiary" means a corporation which is owned or controlled by a parent corporation.

History: Effective September 1, 1986.

General Authority: NDCC 6-01-04

Law Implemented: NDCC 6-03-59

13-02-09-03. Liabilities of a borrower.

1. Standby letters of credit must always be included in determining the total direct, indirect, or contingent liability of a borrower who is a beneficiary of the standby letter of credit.
2. The obligations of a general partnership must always be included in determining the total direct, indirect, or contingent liability of each general partner of the partnership.
3. The obligations of a limited partnership must always be included, to the extent of each limited partner's share of ownership of the limited partnership, in determining the total direct, indirect, or contingent liability of each limited partner of the limited partnership. The entire obligation of a limited partnership must always be included in determining the total direct, indirect, or contingent liability of the general partner of a limited partnership.
4. An extension of credit to a borrower which is participated by the banking association to a third party with recourse must always be included in determining the total direct, indirect, or contingent liability of that borrower.
5. If an extension of credit or loan is secured by a pledged certificate of deposit drawn on the lending bank and payable to the borrower, the face value of the certificate of deposit or the borrower's obligation secured by the certificate of

deposit, whichever is less, may not be considered in determining the total liability of a borrower.

History: Effective September 1, 1986.

General Authority: NDCC 6-01-04

Law Implemented: NDCC 6-03-59

13-02-09-04. Loans to corporations and principals.

1. Obligations of apparent corporation must be combined with obligations of subsidiary corporations in which the parent owns or controls a twenty-five percent or more interest, if one of the conditions in subsection 4 exists.
2. Obligations of subsidiary corporations must be combined, if one of the conditions in subsection 4 exists.
3. Except as provided in subsection 5 of North Dakota Century Code section 13-02-09-05, obligations of an individual who owns or controls a twenty-five percent or more interest in a corporation must be combined with the obligations of said corporation, if one of the conditions in subsection 4 exists.
4. Combining under this section is required if:
 - a. The primary source of repayment for the obligation is the profits or cash flow of the same individual, parent corporation, or other subsidiary.
 - b. One or more loans is for the accommodation of the individual, parent corporation, or other subsidiary.
 - c. The borrowing corporations are not separate concerns, in reality, but merely departments or divisions of a single enterprise.
5. If an extension of credit would otherwise be required to be combined under subsection 3, and the extension of credit is secured by a purchase money security interest for an individual borrower's personal use, or is secured by a first lien on the residence of, and the residence is owned by or is expected to be owned by (after the extension of credit) the borrower, the extension of credit may not be combined.

History: Effective September 1, 1986.

General Authority: NDCC 6-01-04

Law Implemented: NDCC 6-03-59

13-02-09-05. Loans to members of a partnership or association.

Where persons are engaged in a common enterprise, whether in the form of a partnership, joint venture, or other association, individually borrow

funds which are to be used in that enterprise, the loans must be considered as a single extension of credit, unless the bank has established that the enterprise is not the source of repayment.

History: Effective September 1, 1986.

General Authority: NDCC 6-01-04

Law Implemented: NDCC 6-03-59

TITLE 33
Department of Health

JUNE 1986

STAFF COMMENT: Appendices to Article 33-10 are not printed to save space.

33-10-01-04. Definitions. As used in this article, these terms have the definitions set forth below. Additional definitions used only in a certain section will be found in that section. Terms not defined in this article shall have the meaning given them in North Dakota Century Code chapter 23-20.1.

1. "Accelerator produced material" means any material made radioactive by exposing it in a particle accelerator.
2. "Act" means North Dakota Century Code chapter 23-20.1.
3. "Agreement state" means any state with which the United States nuclear regulatory commission has entered into an effective agreement under Section 274(b) of the Atomic Energy Act of 1954, as amended [73 Stat. 688; 42 U.S.C. 2021].
4. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases.
5. "Airborne radioactivity area" means:
 - a. Any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in Appendix A, Table I, Column 1, chapter 33-10-04; or
 - b. Any room, enclosure, or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed twenty-five percent of

the amounts specified in Appendix A, Table I, Column 1, chapter 33-10-04.

6. "Byproduct material" means:
 - a. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
 - b. The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.
7. "Calendar quarter" means not less than twelve consecutive weeks nor more than fourteen consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by the licensee or registrant of determining calendar quarters for purposes of this article except at the beginning of a calendar year.
8. "Calibration" means the determination of:
 - a. The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
 - b. The strength of a source of radiation relative to a standard.
9. "CFR" means Code of Federal Regulations.
- ~~9-~~ 10. "Curie" means a unit of measurement of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^7 dps. One microcurie (uCi) = 0.000001 curie = 3.7×10^4 dps.
- ~~10-~~ 11. "Department" means the North Dakota state department of health.
- ~~11-~~ 12. "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.
- ~~12-~~ 13. "Dose" means absorbed dose or dose equivalent as appropriate:

- a. "Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad. (See "rad")
- b. "Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem. (See "rem")
- ~~13~~ 14. "Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed fifty years.
- ~~14~~ 15. "Exposure" means the quotient of dQ by dm where " dQ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " dm " are completely stopped in air. (The special unit of exposure is the roentgen (R).)
- ~~15~~ 16. "Exposure rate" means the exposure per unit of time, such as R/min, mR/h, etc.
- ~~16~~ 17. "Healing arts" means diagnostic or healing treatment of human and animal maladies including, but not limited to, the following which are duly licensed by the state of North Dakota for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.
- ~~17~~ 18. "High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of one hundred millirems.
- ~~18~~ 19. "Human use" means the internal or external administration of radiation or radioactive material to human beings.
- ~~19~~ 20. "Individual" means any human being.
- ~~20~~ 21. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the department.
22. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

- ~~21-~~ 23. "License" means a general or specific license issued by the department in accordance with the regulations adopted by the department.
- ~~22-~~ 24. "Licensee" means any person who ~~possesses a specific license of~~ is licensed by the department in accordance with this article and North Dakota Century Code chapter 23-20.1.
- ~~23-~~ 25. "Licensing state" means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM.

26. "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A quantity and Type B quantity of radioactive material the aggregate radioactivity of which does not exceed that specified in the following table:

Transport Groups (see Table A)	Type A Quantity (in curies)	Type B Quantity (in curies)
I	0.001	20
II	0.05	20
III	3	200
IV	20	200
V	20	5,000
VI and VIII	1,000	50,000
Special form	20*	5,000

*Except that for californium-252, the limit is 2 Ci.

- ~~24-~~ 27. "NARM" means any naturally occurring or accelerator-produced radioactive material except source material.
- ~~25-~~ 28. "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- ~~26-~~ 29. "Occupational dose" means exposure of an individual to radiation (a) in a restricted area; or (b) in the course of employment in which the individual's duties involve exposure to radiation; provided, that occupational dose shall not be deemed to include any exposure of an individual to radiation for the purpose of diagnosis or therapy of such individual.
- ~~27-~~ 30. "Ore refineries" means all processors of a radioactive material ore.

- ~~28-~~ 31. "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectronvolt.
- ~~29-~~ 32. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the commission, or any successor thereto and other than federal government agencies licensed by the commission or any successor thereto.
- ~~30-~~ 33. "Personnel monitoring equipment" means devices, e.g., film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.
- ~~31-~~ 34. "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.
- ~~32-~~ 35. "Physician" means an individual licensed by this state to dispense drugs in the practice of medicine.
- ~~33-~~ 36. "Rad" means the special unit of absorbed dose. One rad equals one hundredth of a joule per kilogram of material; for example, if tissue is the material of interest, then one rad equals one hundred ergs per gram of tissue.
- ~~34-~~ 37. "Radiation" means ionizing radiation, i.e., gamma rays and X-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.
- ~~35-~~ 38. "Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of five millirems, or in any five consecutive days a dose in excess of one hundred millirems.
- ~~36-~~ 39. "Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.
- ~~37-~~ 40. "Radiation safety officer" means ~~one~~ a person who has the knowledge and responsibility to apply appropriate radiation protection ~~regulations~~ requirements.
- ~~38-~~ 41. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

- ~~39-~~ 42. "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.
- ~~40-~~ 43. "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to this article and North Dakota Century Code chapter 23-20.1.
- ~~41-~~ 44. "Registration" means the notification of the department of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23-20.
- ~~42-~~ 45. "Regulations of the United States department of transportation" means the regulations in 49 CFR, ~~parts~~ 100-189.
- ~~43-~~ 46. "Rem" means a measure of the dose of any radiation to body tissue in terms of its estimated biological effect relative to a dose received from an exposure to one roentgen (R) of X-rays. (one millirem (mrem) = 0.001 rem.) For the purpose of this article, any of the following is considered to be equivalent to a dose of one rem:
- a. An exposure of 1 R of x, or gamma radiation.
 - b. A dose of 1 rad due to x, gamma, or beta radiation.
 - c. A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.
 - d. A dose of 0.1 rad due to neutrons or high energy protons. If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron absorbed dose in rads, one rem of neutron radiation may, for purposes of this article, be assumed to be equivalent to fourteen million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

Neutron Flux Dose Equivalents

Neutron energy (MeV)	Number of neutrons per square centimeter for a dose equivalent of 1 rem (neutrons/cm ²)	Average flux density to deliver 100 millirems in 40 hours (neutrons/cm ² per second)
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Thermal 970 x 10⁶ 670

0.0001	720 x 10 ⁶	500
0.005	820 x 10 ⁶	570
0.02	400 x 10 ⁶	280
0.1	120 x 10 ⁶	80
0.5	43 x 10 ⁶	30
1.0	26 x 10 ⁶	18
2.5	29 x 10 ⁶	20
5.0	26 x 10 ⁶	18
7.5	24 x 10 ⁶	17
10.0	24 x 10 ⁶	17
10 to 30	14 x 10 ⁶	10

~~44-~~ 47. "Research and development" means (a) theoretical analysis, exploration, or experimentation; or (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

~~45-~~ 48. "Restricted area" (controlled area) means any area access to which is controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material. "Restricted area" does not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

~~46-~~ 49. "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulombs per kilogram of air. (See "exposure")

~~47-~~ 50. "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

- ~~48-~~ 51. "Source material" means: (a) uranium or thorium, or any combination thereof, in any physical or chemical form; or (b) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (1) uranium, (2) thorium, or (3) any combination thereof. Source material does not include special nuclear material.
- ~~49-~~ 52. "Source material milling" means any activity that results in the production of byproduct material as defined in subdivision b of subsection 6.
- ~~50-~~ 53. "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
- ~~51-~~ 54. "Special form" means any of the following physical forms of licensed material of any transport group:
- a. The material is in solid form having no dimension less than five-tenths millimeter or at least one dimension greater than five millimeters; does not melt, sublime, or ignite in air at a temperature of one thousand degrees Fahrenheit [540.00 degrees Celsius]; will not shatter or crumble if subjected to the percussion test described in Appendix B to this chapter; and is not dissolved or converted into dispersible form to the extent of more than five-thousandths percent by weight by immersion for one week in water at sixty-eight degrees Fahrenheit [20 degrees Celsius] or in air at eighty-six degrees Fahrenheit [30 degrees Celsius]; or
 - b. The material is securely contained in a capsule having no dimension less than five-tenths millimeter or at least one dimension greater than five millimeters, which will retain its contents if subjected to the tests prescribed in Appendix B to this chapter; and which is constructed of materials which do not melt, sublime, or ignite in air at one thousand four hundred seventy-five degrees Fahrenheit [807.22 degrees Celsius], and do not dissolve or convert into dispersible form to the extent of more than five-thousandths percent by weight by immersion for one week in water at sixty-eight degrees Fahrenheit [20 degrees Celsius] or in air at eighty-six degrees Fahrenheit [30 degrees Celsius].
- ~~52-~~ 55. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding three hundred fifty grams of contained U-235, uranium-233 in quantities not exceeding two hundred grams; plutonium in quantities not exceeding two hundred grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that

special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1", i.e., unity. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

- ~~53-~~ 56. "Survey" means an evaluation of the production, use, release, disposal, or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination, and measurements of levels of radiation or concentration of radioactive material present.
- ~~54-~~ 57. "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.
- ~~55-~~ 58. "These ~~regulations~~ rules" means all parts of this article and any subsequent changes or additions thereto.
- ~~56-~~ 59. "Transport group" means any one of seven groups into which radionuclides in normal form are classified, according to their toxicity and their relative potential hazard in transport, in Appendix A to this chapter.
- a. Any radionuclide not specifically listed in one of the groups in Appendix A shall be assigned to one of the groups in accordance with the following table:

Radionuclide	Radioactive Half-Life		
	0 to 1000 days	1000 days to 10 ⁶ years	Over 10 ⁶ years
Atomic number 1-81	Group III	Group II	Group III
Atomic number 82 and over	Group I	Group I	Group III

- b. For mixtures of radionuclides the following shall apply:
- (1) If the identity and respective activity of each radionuclide are known, the permissible activity of each radionuclide shall be such that the sum, for all groups present, of the ratio between the total

activity for each group to the permissible activity for each group will not be greater than unity.

- (2) If the groups of the radionuclides are known but the amount in each group cannot be reasonably determined, the mixture shall be assigned to the most restrictive group present.
- (3) If the identity of all or some of the radionuclides cannot be reasonably determined, each of those unidentified radionuclides shall be considered as belonging to the most restrictive group which cannot be positively excluded.
- (4) Mixtures consisting of a single radioactive decay chain where the radionuclides are in the naturally occurring proportions shall be considered as consisting of a single radionuclide. The group and activity shall be that of the first member present in the chain, except that if a radionuclide "X" has a half-life longer than that of that first member and an activity greater than that of any other member, including the first, at any time during transportation, the transport group of the nuclide "X" and the activity of the mixture shall be the maximum activity of that nuclide "X" during transportation.

57- 60. "United States department of energy" means the department of energy established by Public Law No. 95-91 [91 Stat. 565; 42 U.S.C. 7101 et seq.] to the extent that the department exercises functions formerly vested in the United States atomic energy commission, its chairman, members, officers, and components and transferred to the United States energy research and development administration and to the administrators thereof pursuant to sections 104(b), (c), and (d) of the Energy Reorganization Act of 1974 [Pub. L. 93-438; 88 Stat. 1237, effective January 19, 1975] and transferred to the secretary of energy pursuant to subsection 301(a) of the Department of Energy Organization Act [Pub. L. 95-91; 91 Stat. 577-578; 42 U.S.C. 7151, effective October 1, 1977].

58- 61. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

59- 62. "Unrestricted area" (uncontrolled area) means any area access to which is not controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

~~60-~~ 63. "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

~~61-~~ 64. "Worker" means an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant, but does not include the licensee or registrant.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-01-09. Additional requirements. The department may, by rule, ~~regulation,~~ or order, impose upon any licensee or registrant such requirements in addition to those established in this article as it deems appropriate or necessary to minimize danger to public health and safety or property.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 23-20.1-03

33-10-01-10. Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of North Dakota Century Code chapter 23-20.1 or any ~~regulations~~ rules or order issued thereunder. Any person who violates any provision of North Dakota Century Code chapter 23-20.1 or any ~~regulation~~ rule or order issued thereunder, and, upon conviction thereof, may be punished as provided by law.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-01-13. Communications. All communications and reports concerning this article and applications filed thereunder shall be addressed to the department at its office located at 1200 Missouri Avenue, Box 5520, Bismarck, North Dakota, ~~58505~~ 58502-5520; Telephone (701) 224-2348, or telegraph North Dakota State Department of Health, State Capitol, Bismarck, North Dakota.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-02-04. Application for registration of servicing and services.

1. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state to a department licensee or registrant shall apply for registration of such services with the department within thirty days following the effective date of this chapter or thereafter prior to furnishing or offering to furnish any such services.
2. Application for registration shall be completed on forms furnished by the department and shall contain all information required by the department as indicated on the forms and accompanying instructions.
3. Each person applying for registration under this chapter shall specify:
 - a. That the person has read and understands the requirements of this chapter.
 - b. The services for which the person is applying for registration.
 - c. The training and experience that qualify the person to discharge the services for which the person is applying for registration.
 - d. The type of measurement instrument to be used, frequency of calibration, and source of calibration.
 - e. The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.
4. For the purpose of this section, services may include, but shall not be limited to:
 - a. Installation or servicing, or both, of radiation machines and associated radiation machine components.
 - b. Calibration of radiation machines or radiation measurement instruments or devices.
 - c. Radiation protection or health physics consultations or surveys.
 - d. Personnel dosimetry services.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-02-05. Issuance of notice of registration.

1. Upon a determination that an applicant meets the requirements of the article, the department shall issue a notice of registration.
2. The department may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, ~~regulation,~~ or order such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-02-11. Out-of-state radiation machines.

1. a. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the department at least ~~five~~ three days before such machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use, and, the exact location where the radiation machine is to be used, the names and addresses where the machine users can be reached while in the state, and the annual fee of forty dollars.
- b. If, for a specific case, the ~~five-day~~ three-day notification period would impose an undue hardship on the person, upon application to the department, permission to proceed sooner may be granted.
2. In addition, the out-of-state person shall do all of the following:
 - a. Comply with ~~all~~ of this article.
 - b. Supply the department with such other information as the department may ~~reasonably~~ request.
 - c. ~~Not operate within the state on a temporary basis, in excess of one hundred eighty calendar days per year.~~ Reapply for reciprocity privileges or apply for registration by the department at the termination of the one-year reciprocity period.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-03-01. Purpose and scope.

1. This chapter provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in this chapter.
2. In addition to the requirements of this chapter, all licensees are subject to the requirements of chapters 33-10-01, 33-10-04, and 33-10-10. Licensees engaged in industrial radiographic operations are subject to the requirements of chapter 33-10-05 and, licensees using sealed sources in the healing arts are subject to the requirements of chapter 33-10-07, and licensees engaged in wire line and subsurface tracer studies are subject to the requirements of chapter 33-10-12.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-03-02. Exemptions.

1. Source material.
 - a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one percent of the mixture, compound, solution, or alloy.
 - b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided, that except as authorized in a specific license, such person shall not refine or process such ore.
 - c. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers:
 - (1) Any quantities of thorium contained in:
 - (a) Incandescent gas mantles.
 - (b) Vacuum tubes.
 - (c) Welding rods.

- (d) Electric lamps for illuminating purposes provided that each lamp does not contain more than fifty milligrams of thorium.
 - (e) Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium.
 - (f) Rare earth metals and compounds, mixtures, and products containing not more than one-fourth of one percent by weight thorium, uranium, or any combination of these.
 - (g) Personnel neutron dosimeters, provided that each dosimeter does not contain more than fifty milligrams of thorium.
- (2) Source material contained in the following products:
- (a) Glazed ceramic tableware, provided that the glaze contains not more than twenty percent by weight source material.
 - (b) Glassware, glass enamel, and glass enamel frit containing not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass enamel or ceramic used in construction.
 - (c) Piezoelectric ceramic containing not more than two percent by weight source material.
- (3) Photographic film, negatives, and prints containing uranium or thorium.
- (4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that the exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.
- (5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that all of the following are met:

- (a) The counterweights are manufactured in accordance with a specific license issued by the United States nuclear regulatory commission authorizing distribution by the licensee pursuant to 10 CFR ~~part~~ 40.
 - (b) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM". This requirement need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM".
 - (c) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED". This requirement need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM".
 - (d) The exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.
- (6) Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and which meets the specifications for containers for radioactive material prescribed in 49 CFR 173.394 or 173.395 of United States department of transportation regulations.
- (7) Thorium contained in finished optical lenses, provided that each lens does not contain more than thirty percent by weight of thorium, and that the exemption contained in this paragraph shall not be deemed to authorize either:
- (a) The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or
 - (b) The receipt, possession, use, or transfer of thorium contained in contact lenses, or in

spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than five-thousandths microcurie of uranium.

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that all of the following are met:

(a) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide).

(b) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

d. The exemptions in subdivision c do not authorize the manufacture of any of the products described.

2. Radioactive material other than source material.

a. Exempt concentrations.

(1) Except as provided in paragraph 2, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires products ~~or materials~~ containing radioactive material introduced in concentrations not in excess of those listed in Schedule A of this chapter.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under paragraph 1 or equivalent regulations of the United States nuclear regulatory commission or any agreement state or licensing state, except in accordance with a specific license issued pursuant to subdivision a of subsection 5 of section 33-10-03-05 or the general license provided in subsection 1 of section 33-10-03-06.

b. Exempt quantities.

(1) Except as provided in paragraphs 2 and 3, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the

applicable quantity set forth in Schedule B of this chapter.

- (2) This subdivision does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
- (3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this subdivision or equivalent regulations of the United States nuclear regulatory commission, any agreement state, or a licensing state, except in accordance with a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.18 or by the department pursuant to subdivision b of subsection 5 of section 33-10-03-05 which license states that the radioactive material may be transferred by the licensee to persons exempt under this subdivision or the equivalent regulations of the United States nuclear regulatory commission, any agreement state, or a licensing state.

c. Exempt items.

- (1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States nuclear regulatory commission, Washington, D.C. 20555):
 - (a) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified ~~levels~~ of radiation dose rates:

- [1] Twenty-five millicuries of tritium per timepiece.
 - [2] Five millicuries of tritium per hand.
 - [3] Fifteen millicuries of tritium per dial (bezels when used shall be considered as part of the dial).
 - [4] One hundred microcuries of promethium-147 per watch or two hundred microcuries of promethium-147 per any other timepiece.
 - [5] Twenty microcuries of promethium-147 per watch hand or forty microcuries of promethium-147 per other timepiece hand.
 - [6] Sixty microcuries of promethium-147 per watch dial or one hundred twenty microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).
 - [7] The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through fifty milligrams per square centimeter of absorber:
 - [a] For wristwatches, one-tenth millirad per hour at ten centimeters from any surface.
 - [b] For pocket watches, one-tenth millirad per hour at one centimeter from any surface.
 - [c] For any other timepiece, two-tenths millirad per hour at ten centimeters from any surface.
 - [8] One microcurie of radium-226 per timepiece in timepieces acquired prior to the effective date of these regulations this article.
- (b) Lock illuminators containing not more than fifteen millicuries of tritium or not more than two millicuries of promethium-147 installed in automobile locks. The levels of radiation dose rate from each lock illuminator containing promethium-147 will not exceed one millirad per hour at one centimeter from any surface when

measured through fifty milligrams per square centimeter of absorber.

- (c) Balances of precision containing not more than one millicurie of tritium per balance or not more than five-tenths millicurie of tritium per balance part.
- (d) Automobile shift quadrants containing not more than twenty-five millicuries of tritium.
- (e) Marine compasses containing not more than seven hundred fifty millicuries of tritium gas and other marine navigational instruments containing not more than two hundred fifty millicuries of tritium gas.
- (f) Thermostat dials and pointers containing not more than twenty-five millicuries of tritium per thermostat.
- (g) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct material:
 - [1] One hundred fifty millicuries of tritium per microwave receiver protector tube or ten millicuries of tritium per any other electron tube.
 - [2] One microcurie of cobalt-60.
 - [3] Five microcuries of nickel-63.
 - [4] Thirty microcuries of krypton-85.
 - [5] Five microcuries of cesium-137.
 - [6] Thirty microcuries of promethium-147.

And provided further, that the levels of radiation dose rate from each electron tube containing byproduct material do not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(h) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material; provided, that:

[1] Each source contains no more than one exempt quantity set forth in Schedule B of this chapter; and

[2] Each instrument contains no more than ten exempt quantities. For purposes of this subparagraph an instrument's source may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(i) Spark gap irradiators containing not more than one microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons [11.4 liters] per hour.

(2) Self-luminous products containing radioactive material.

(a) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemptions in this paragraph do not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(b) Radium-226. Any person is exempt from this article to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than one-tenth microcurie of radium-226 which were acquired prior to the effective date of this article.

(3) Gas and aerosol detectors containing radioactive material.

(a) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the United States nuclear regulatory commission or a licensing state, pursuant to 10 CFR 32.26, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States nuclear regulatory commission, Washington, D.C. 20555.)

(b) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under subparagraph a, provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that they meet the requirements of subdivision c of subsection 5 of section 33-10-03-05.

(c) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under subparagraph a, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of subsection 5 of section 33-10-03-05.

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from this chapter to the extent that such person

receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the United States nuclear regulatory commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in 10 CFR 32.16 and 32.17 of the regulations of the United States nuclear regulatory commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-03-04. General licenses.

1. General licenses - source material.

- a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, state and local government agencies to use and transfer not more than fifteen pounds [6.80 kilograms] of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of one hundred fifty pounds [68.04 kilograms] of source material in any one calendar year.
- b. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in subdivision a shall not receive more than a total of one hundred fifty pounds [68.04 kilograms] of source material in any one calendar year.
- c. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in subdivision a are exempt from the provisions of chapters 33-10-04 and 33-10-10 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this chapter.

d. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

e. Depleted uranium in industrial products and devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with paragraphs 2, 3, 4, and 5, of depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of a product or device.

(2) The general license in paragraph 1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to or in accordance with a specific license issued to the manufacturer by the United States nuclear regulatory commission or an agreement state which authorizes ~~manufacture~~ manufacture of the products or devices for distribution to persons generally licensed by the United States nuclear regulatory commission or an agreement state.

(3) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph 1 shall file form RAD 811 "registration certificate - use of depleted uranium under general license" with the department. The form shall be submitted within thirty days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish the following information and such other information as may be required by that form:

[1] Name and address of the registrant.

[2] A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in paragraph 1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

[3] Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in

supervising the procedures identified in paragraph 1.

- (b) The registrant possessing or using depleted uranium under the general license established by paragraph 1 shall report in writing to the department any changes in information furnished by the registrant in form RAD 811 "registration certificate - use of depleted uranium under general license". The report shall be submitted within thirty days after the effective date of such change.
- (4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph 1:
- (a) May not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.
 - (b) May not abandon such depleted uranium.
 - (c) Shall transfer or dispose of such depleted uranium only by transfer in accordance with subsection 14 of section 33-10-03-05. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph 1, the transferor shall furnish the transferee a copy of this ~~regulation~~ section and a copy of form RAD 811. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the United States nuclear regulatory commission's or agreement state's regulation equivalent to paragraph 1, the transferor shall furnish the transferee a copy of this ~~regulation~~ section and a copy of form RAD 811 accompanied by a note explaining that use of the product or device is regulated by the United States nuclear regulatory commission or agreement state under requirements substantially the same as those in this ~~regulation~~ article.
 - (d) Within thirty days of any transfer, shall report in writing to the department the name and address of the person receiving the depleted uranium pursuant to such transfer.

(e) May not export such depleted uranium except in accordance with a license issued by the United States nuclear regulatory commission pursuant to 10 CFR **part** 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph 1 is exempt from the requirements of chapters 33-10-04 and 33-10-10 **and these** with respect to the depleted uranium covered by that general license.

2. **General licenses - radioactive material other than source material.**

a. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer pursuant to subdivision f of subsection 5 of section 33-10-03-05 or its equivalent by the department, the United States nuclear regulatory commission, any agreement state, or a licensing state, and authorizing distribution under this general license or its equivalent. This general license is subject to the provisions of sections 33-10-01-06 through 33-10-01-11, paragraph 2 of subdivision a of subsection 2 of section 33-10-03-02, **subsections subsection 7, 14, and 15** of section 33-10-03-05, section 33-10-03-07, and chapters 33-10-04 and 33-10-10. (Attention is directed particularly to the provisions of chapter 33-10-04 which relate to the labeling of containers.)

(1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than five hundred microcuries of polonium-210 per device.

(2) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than five hundred microcuries of polonium-210 per device or a total of not more than fifty millicuries of hydrogen-3 (tritium) per device.

b. Certain measuring, gauging, and controlling devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of

their business, and state or local government agencies to own, receive, acquire, possess, use, or transfer in accordance with the provisions of paragraphs 1, 2, and 3, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

- (2) The general license in paragraph 1 applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to subdivision d of subsection 5 of section 33-10-03-05 or in accordance with the specifications contained in a specific license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state which authorizes distribution of devices to persons generally licensed by the nuclear regulatory commission, an agreement state, or a licensing state. (Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.)
- (3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in paragraph 1:
 - (a) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels.
 - (b) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:
 - [1] Devices containing only krypton need not be tested for leakage of radioactive material.
 - [2] Devices containing only tritium or not more than one hundred microcuries of other beta

or gamma emitting material or ten microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

- (c) Shall assure that the tests required by subparagraph b of paragraph 1 of this subdivision and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:
- [1] In accordance with the instructions provided by the labels; or
 - [2] By a person holding a specific license from the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to perform such activities.
- (d) Shall maintain records showing compliance with the requirements of subparagraphs b and c. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment.
- (e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of five-thousandths microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within thirty days, furnish to the department a report containing a brief description of the event and the remedial action taken.

- (f) Shall not abandon the device containing radioactive material.
- (g) Except as provided in subparagraph h, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the United States nuclear regulatory commission, an agreement state, or a licensing state whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device.
- (h) Shall transfer the device to another general licensee only:
- [1] Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this chapter and any safety documents identified in the label on the device and within thirty days of the transfer, report to the department the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name or position of an individual who may constitute a point of ~~contract~~ contact between the department and the transferee; or
- [2] Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.
- (i) Shall comply with the provisions of subsections 2 and 3 of section 33-10-04-05 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of chapters 33-10-04 and 33-10-10.
- (4) The general license in paragraph 1 does not authorize the manufacture of devices containing radioactive material.

- (5) The general license provided in paragraph 1 is subject to the provisions of sections 33-10-01-01 through 33-10-01-11, subsections 7, 14, and 15 of section 33-10-03-05, and section 33-10-03-07.

c. Luminous safety devices for aircraft.

- (1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided all of the following are met:
 - (a) Each device contains not more than ten curies of tritium or three hundred millicuries of promethium-147.
 - (b) Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the United States nuclear regulatory commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.53 of the regulations of the United States nuclear regulatory commission.
- (2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to paragraph 1 are exempt from the requirements of chapters 33-10-04 and 33-10-10 except that they shall comply with the provisions of subsections 2 and 3 of section 33-10-04-05.
- (3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.
- (4) This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium-147 contained in instrument dials.
- (5) This general license is subject to the provisions of sections 33-10-01-01 through 33-10-01-11, subsections 7, 14, and 15 of section 33-10-03-05, and section 33-10-03-07.

- d. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the

manufacture, production, transfer, receipt, possession, or use of radioactive material.

e. Calibration and reference sources.

- (1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs 3 and 4, americium-241 in the form of calibration or reference sources:
 - (a) Any person who holds a specific license issued by the department which authorizes the person to receive, possess, use, and transfer radioactive material.
 - (b) Any person who holds a specific license issued by the United States nuclear regulatory commission which authorizes him to receive, possess, use, and transfer special nuclear material.
- (2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs 3 and 4 to any person who holds a specific license issued by the department which authorizes the person to receive, possess, use, and transfer radioactive material.
- (3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of paragraphs 4 and 5 to any person who holds a specific license issued by the department which authorizes the person to receive, possess, use, and transfer radioactive material.
- (4) The general licenses in paragraphs 1 and 2 apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States nuclear regulatory commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39 of the regulations of the United States nuclear regulatory commission.

←4→ (5) The general licenses provided in paragraphs 1 and, 2, and 3 are subject to the provisions of sections 33-10-01-06 through 33-10-01-11, subsections 7, 14, and 15 of section 33-10-03-05, section 33-10-03-07, and chapters 33-10-04 and 33-10-10. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) Shall not possess at any one time, at any one location of storage or use, more than five microcuries of americium-241 and, five microcuries of plutonium, or five microcuries of radium-226 in such sources.

(b) Shall not receive, possess, use, or transfer such source unless the source, or the storage container; bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

[1] The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

[2] The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any licensing state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS ~~(AMERICIUM-241)~~ ~~(PLUTONIUM)~~ (RADIUM-226) (Showing only the name of the appropriate material.) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

- (c) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the department, the United States nuclear regulatory commission, ~~or~~ an agreement state, or a licensing state to receive the source.
 - (d) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 ~~or~~ , plutonium, or radium-226 which might otherwise escape during storage.
 - (e) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
- (5) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.
- f. Medical diagnostic uses. (Subdivision f of subsection 5 of section 33-10-03-05 requires manufacturers of radiopharmaceuticals which are under the general license in this subdivision to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical. The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)
- (1) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of paragraphs 2, 3, and 4, the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued pursuant to subdivision g of subsection 5 of section 33-10-03-05 by the department, the United States nuclear regulatory

commission, any agreement state, or licensing state authorizing distribution under the general license granted in this subdivision or its equivalent:

- (a) Iodine-131 as sodium iodide (Na^{131}I) for measurement of thyroid uptake.
 - (b) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.
 - (c) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.
 - (d) Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin.
 - (e) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin.
 - (f) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin.
 - (g) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.
- (2) No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by paragraph 1 until the physician has filed Department Form RAD 684, "Certificate - Medical Use of Radioactive Material Under General License" with the department and received from the department a validated copy of the Department Form RAD 684 with certification number as signed. The generally licensed physician shall furnish on Department Form RAD 684 the following information and such other information as may be required by that form:
- (a) Name and address of the generally licensed physician.
 - (b) A statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in this state.
 - (c) A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which the physician proposes to use radioactive material under the general

license of this paragraph and that the physician is competent in the use of such instruments.

- (3) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by paragraph 1 shall comply with the following:
 - (a) The physician shall not possess at any one time, pursuant to the general license in paragraph 1 more than:
 - [1] Two hundred microcuries of iodine-131.
 - [2] Two hundred microcuries of iodine-125.
 - [3] Five microcuries of cobalt-57.
 - [4] Five microcuries of cobalt-58.
 - [5] Five microcuries of cobalt-60.
 - [6] Two hundred microcuries of chromium-51.
 - (b) The physician shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection.
 - (c) The physician shall use the pharmaceutical only for the uses authorized by paragraph 1.
 - (d) The physician shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under eighteen years of age.
 - (e) The physician shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States nuclear regulatory commission, any agreement state or a licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.
- (4) The generally licensed physician possessing or using radioactive material under the general license of paragraph 1 shall report in duplicate to the department, any changes in the information furnished by the physician in the "Certificate - Medical Use of Radioactive Material Under General License",

Department Form RAD 684. The report shall be submitted within thirty days after the effective date of such change.

- (5) Any person using radioactive material pursuant to the general license of paragraph 1 is exempt from the requirements of chapters 33-10-04 and 33-10-10 with respect to the radioactive material covered by the general license.
- g. General license for use of radioactive material for certain in vitro clinical or laboratory testing. (The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)
- (1) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs 2, 3, 4, 5, and 6, the following radioactive materials in prepackaged units:
 - (a) Iodine-125, in units not exceeding ten microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (b) Iodine-131, in units not exceeding ten microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (c) Carbon-14, in units not exceeding ten microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (d) Hydrogen-3 (tritium), in units not exceeding fifty microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

- (e) Iron-59, in units not exceeding twenty microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (f) Cobalt-57, in units not exceeding ten microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (g) Selenium-75, in units not to exceed ten microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
 - (h) Mock iodine-125 reference or calibration sources, in units not exceeding five-hundredths microcurie of iodine-129 and five-thousandths microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (2) No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by paragraph 1 until the person has filed Department Form RAD 732, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the department and received from the department a validated copy of Department Form RAD 732 with certification number as signed. The physician, veterinarian, clinical laboratory, or hospital shall furnish on Department Form RAD 732 the following information and such other information as may be required by that form:
- (a) Name and address of the physician, veterinarian, clinical laboratory, or hospital.
 - (b) The location of use.
 - (c) A statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the

general license in paragraph 1 and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

- (3) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by paragraph 1 shall comply with the following:
 - (a) The general licensee shall not possess at any one time, pursuant to the general license in paragraph 1 at any one location of storage or use a total amount of iodine-125, iodine-131, selenium-75, iron-59 ~~or~~ and/or cobalt-57 in excess of two hundred microcuries.
 - (b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - (c) The general licensee shall use the radioactive material only for the uses authorized by paragraph 1.
 - (d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States nuclear regulatory commission, any agreement state, or a licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 - (e) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in subparagraph h of paragraph 1 as required by subsection 1 of section 33-10-04-04.
- (4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to paragraph 1.
 - (a) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the United States nuclear regulatory commission, any agreement state, or a licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to

persons generally licensed under this paragraph or its equivalent; and

- (b) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

[1] This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations this article and a general license of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

[2] This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations this article and a general license of a licensing state.

Name of manufacturer

- (5) The physician, veterinarian, clinical laboratory, or hospital possessing or using radioactive material under the general license of paragraph 1 shall report, in writing, to the department, any changes in the information furnished by the physician, veterinarian, clinical laboratory, or hospital in the "Certificate - In Vitro Testing with Radioactive

Material Under General License", Department Form RAD 732. The report shall be furnished within thirty days after the effective date of such change.

- (6) Any person using radioactive material pursuant to the general license of paragraph 1 is exempt from the requirements of chapters 33-10-04 and 33-10-10 with respect to radioactive material covered by that general license.

h. Ice detection devices.

- (1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the United States nuclear regulatory commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.61 of the regulations of the United States nuclear regulatory commission.
- (2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph 1.
 - (a) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the United States nuclear regulatory commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of subsection 1.
 - (b) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon.
 - (c) Are exempt from the requirements of chapters 33-10-04 and 33-10-10 except that such persons shall comply with the provisions of subsection 1 of section 33-10-04-04, and subsections 2 and 3 of section 33-10-04-05.

- (3) This general license does not authorize the manufacture, assembly, disassembly, or repair of strontium-90 in ice detection devices.
- (4) This general license is subject to the provisions of sections 33-10-01-06 through 33-10-01-11, subsections 7, 14, and 15 of section 33-10-03-05, and section 33-10-03-07.

i. General licensed quantities for radium-226.

- (1) A general license is hereby issued to commercial and industrial firms, and to research, educational, medical, and governmental institutions to own, receive, acquire, possess, use, and transfer radium-226 in units not exceeding one-tenth microcurie each in accordance with the provisions of paragraphs 2, 3, and 4.
- (2) No such person shall receive, acquire, possess, use, or transfer radium-226 pursuant to the general license established by paragraph 1 until the person has filed Department Form RAD 761 "Certificate - Radium-226 Under General License", with the department and has received from the department a validated copy of Department Form RAD 761 with certification number assigned. The person identified in paragraph 1 shall furnish in Department Form RAD 761 the following information and such other information as may be required by that form:
 - (a) Name and address of the person identified in paragraph 1.
 - (b) The location of use.
 - (c) A statement that such person has appropriate radiation measuring instruments to carry out an adequate program of radiation protection and that the use of authorized material will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.
- (3) A person who receives, acquires, possesses, or uses radium-226 pursuant to the general license established by paragraph 1 shall comply with the following:
 - (a) The general licensee shall not possess at any one time, pursuant to the general license in paragraph 1 at any one location of storage or

use, a total amount of radium-226 in excess of five microcuries.

- (b) The general licensee shall store the radium-226, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - (c) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, or any agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the shipper.
 - (d) The person possessing or using the radioactive material under the general license of paragraph 1 shall report, in writing, to the department, any changes in the information furnished by the person in the "Certificate - Radium-226 Under General License", Department Form RAD 761. The report shall be furnished within thirty days after the effective date of such change.
 - (e) Any person using radium-226 pursuant to the general license of paragraph 1 is exempt from the requirements of chapters 33-10-04 and 33-10-10 with respect to the radioactive material covered by the general license.
- (4) This general license does not authorize the manufacture, commercial distribution, or human use of radium-226.

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

General Authority: NDCC 28-32-04

Law Implemented: NDCC 23-20.1-04

33-10-03-05. Specific licenses.

1. Filing application for specific licenses.

- a. Applications for specific licenses shall be filed in triplicate on a form prescribed by the department.
- b. The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

- c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.
- d. An application for a license may include a request for a license authorizing one or more activities.
- e. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the department provided such references are clear and specific.
- f. Applications and documents submitted to the department shall be made available for public inspection except that the department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.
- g. Each application for a specific license shall be accompanied by the fee prescribed in chapter 33-10-11.

2. **General requirements for the issuance of specific licenses.** A license will be granted if the department determines all of the following:

- a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this chapter in such a manner as to minimize danger to public health and safety or property.
- b. The applicant has a permanent in-state office.
- c. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property.
- ~~e~~ d. The issuance of the license will not be inimical to the health and safety of the public.
- ~~d~~ e. The applicant satisfies any applicable special requirements in subsections 3, 4, or 5.
- ~~e~~ f. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the department determines will significantly affect the quality of the environment, the department, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical, and other benefits

against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

g. Financial surety arrangements.

- (1) Pursuant to subsection 2 of North Dakota Century Code section 23-20.1-04 ~~of the North Dakota Century Code~~ and except as otherwise provided, financial surety arrangements for site reclamation and long-term surveillance and control which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in paragraph 4 shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the North Dakota Century Code and this article.
 - (a) The amount of funds to be ensured by such surety arrangements shall be based on department-approved cost estimates.
 - (b) 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.
- (2) The arrangements required in paragraph 1 shall be established prior to commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.
- (3) Amendments to licenses in effect on ~~(the effective date of this section)~~ October 1, 1982, may be

issued providing that the required surety arrangements are established within ninety days after the effective date of this subdivision October 1, 1982.

- (4) The following specific licensees are required to make financial surety arrangements:
- (a) Major processors.
 - (b) Waste handling licensees.
 - (c) Former United States atomic energy commission or United States nuclear regulatory commission licensed facilities.
 - (d) Source material milling operations.
 - (e) All others except persons exempt pursuant to paragraph 6.
- (5) For source material milling operations, the amount of funds to be ensured by such surety arrangements shall be based on department-approved cost estimates in an approved plan for (a) decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and (b) the reclamation of tailings or waste disposal areas in accordance with the technical criteria delineated in chapter 33-10-03. 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 alternative alternatives for mitigating these impacts. In addition, the surety shall cover the payment of the charge for long-term surveillance and control required by the department. In establishing specific surety arrangements, the licensee's ~~costs~~ cost estimates shall 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, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommission and reclamation

of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the department to assure that sufficient funds will 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 shall 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 could 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) 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 department to collect.

- (6) The following persons are exempt from the requirements of paragraph 1:
- (a) All state, local, or other government agencies, unless they are subject to subparagraph a or b of paragraph 4.
 - (b) Persons authorized to possess no more than one thousand times the quantity specified in Schedule B, Exempt Quantities, or combination of radioactive material listed therein as given in ~~note 17~~ Schedule B.
 - (c) Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source.

(d) Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than thirty days.

(7) The requirements of paragraph 1 will not be applicable to uranium mill tailings licensees after September 30, 1983, or whenever this state obtains an amended agreement with the United States nuclear regulatory commission pursuant to the Uranium Mill Tailings Radiation Control Act of 1978, as amended [42 U.S.C. 7901 et seq.].

~~g-~~ h. Long-term care requirements. Pursuant to North Dakota Century Code section 23-20.1-04, and as otherwise provided, a long-term care trust fund shall be established by the following specific licensees prior to the issuance of the license. (Long-term care funding may also be required for former United States atomic energy commission or United States nuclear regulatory commission licensed facilities.)

(1) Waste handling licensees.

(2) Source material milling licensees.

~~h-~~ i. Continued surveillance requirements for source material mills.

(1) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the department retaining ultimate custody of the site where tailings, or wastes are stored to confirm the integrity of the stabilized tailings, or waste systems and to determine the need, if any, for maintenance or monitoring. Results of the inspection shall be reported to the United States nuclear regulatory commission within sixty days following each inspection, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

(2) A minimum charge of two hundred fifty thousand dollars (1978 dollars) to cover the costs of long-term surveillance shall be paid by each mill operator to the department 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 paragraph 1, e.g., if fencing is determined to be necessary, variance in funding requirements may be specified by the department. The total charge to cover the costs of long-term surveillance shall 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 charge will be adjusted annually prior to actual payments 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.

3. Special requirements for issuance of certain specific licenses for radioactive material.

a. Human use of radioactive material in institutions. In addition to the requirements set forth in subsection 2, a specific license for human use of radioactive material in institutions will be issued if all of the following are met:

- (1) The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee shall include a physician recognized as a specialist in nuclear medicine, a person with a special competence in radiation safety, and a representative of the institution's management.
- (2) The applicant possesses adequate facilities for the clinical care of patients.
- (3) The physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.
- (4) If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

b. Licensing of individual physicians for human use of radioactive material.

- (1) An application by an individual physician or group of physicians for a specific license for human use of

radioactive material will be approved if all of the following are met:

- (a) The applicant satisfies the general requirements specified in subsection 2.
 - (b) The application is for use in the applicant's private practice in the applicant's private office.
 - (c) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable.
 - (d) The applicant has extensive experience in the proposed use, the handling and administration of radioactive material, and where applicable, the clinical management of radioactive patients. (The physician shall furnish suitable evidence of such experience with the application. A statement from the medical isotopes committee in the institution where the physician acquired experience, indicating its amount and nature, may be submitted as evidence of such experience.)
- (2) The department will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a hospital or clinic unless:
- (a) The use of radioactive material is limited to:
 - [1] The administration of radiopharmaceuticals for diagnostic or therapeutic purposes.
 - [2] The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered.
 - [3] The performance of in vitro diagnostic studies.
 - [4] The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation.
 - (b) The physician brings the radioactive material with the physician and removes the radioactive material when the physician departs. (The

institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient.)

- (c) The medical institution does not hold a radioactive material license under subdivision a.

c. Specific licenses for certain groups of medical uses of radioactive material.

- (1) Subject to the provisions of paragraphs 2, 3, and 4, an application for a specific license pursuant to subdivision a or b for any medical use or uses of radioactive material specified in one or more of Groups I through VI of Schedule C of this chapter will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

- (a) The applicant satisfies the requirements of subdivisions a, b, and d.

- (b) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups.

- (c) The applicant or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups.

- (d) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups.

- (e) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

- (2) Any licensee who is authorized to use radioactive material pursuant to one or more groups in paragraph 1 and Schedule C of this chapter is subject to the following conditions:

- (a) For Groups I, II, IV, and V, no licensee shall receive, possess, or use radioactive material

except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with a specific license issued by the department pursuant to subdivision j of subsection 5, a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.72, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

- (b) For Group III, no licensee shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

[1] Reagent kits not containing radioactive material that are approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state for use by persons licensed pursuant to this subdivision and Schedule C of this chapter or equivalent regulations.

[2] Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the department pursuant to subdivision k of this subsection, a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.73, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

- (c) For Group VI, no licensee shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the department pursuant to subdivision l of subsection 5, a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.74, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(d) For Group III, any licensee using generators or reagent kits shall:

[1] Elute the generator, or process radioactive material with the reagent kit, in accordance with instructions approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or ~~aging~~ reagent kit.

[2] Before administration to patients, cause each elution or extraction of technetium-99m generator to be tested to determine either the total molybdenum-99 activities or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test.

[3] Prohibit the administration to patients of technetium-99m containing more than one microcurie of molybdenum-99 per millicurie of technetium-99m, or more than five microcuries of molybdenum-99 per ~~administer~~ administered dose, at the time of administration.

[4] Maintain for department inspection records of the molybdenum-99 test conducted on each elution from the generator.

(e) For Group VI any licensee who possesses and uses sources or devices containing radioactive material shall:

[1] Cause each source or device containing more than one hundred microcuries of radioactive material with a half-life greater than thirty days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination or leakage at intervals not to exceed six months or at such other intervals as are approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state and described by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure

which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer.

- [2] Assure that the test required by item 1 of this subparagraph shall be capable of detecting the presence of five-thousandths microcurie of radioactive material on the test sample or in the case of radium, the escape of radon at the rate of one-thousandths microcurie per twenty-four hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department.
- [3] If the test required by item 1 of this subparagraph reveals the presence of five-thousandths microcurie or more of removable contamination or in the case of radium, the escape of radon at the rate of one-thousandths microcurie per twenty-four hours, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with department regulations this article. A report shall be filed within five days of the test with the department, describing the equipment involved, the test results, and the corrective action taken.
- [4] Follow the radiation safety and handling instructions approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.
- [5] Conduct a quarterly physical inventory to account for all sources and devices

received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.

[6] Assure that needles or standard medical applicator cells containing radium-226, or cobalt-60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued by the department.

[7] Assure that patients treated with cobalt-60, cesium-137, ~~iridium-192~~ iridium-192, or radium-226 implants remain hospitalized until a source count and a radiation survey ~~of~~ of the patient confirms that all implants have been removed.

(f) For groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

[1] Chemical and physical form.

[2] Route of administration.

[3] Dosage range.

(3) Any licensee who is licensed pursuant to paragraph 1 for one or more of the medical use groups in Schedule C also is authorized to use radioactive material under the general license in subdivision g of subsection 2 of section 33-10-03-04 for the specified in vitro uses without filing Form RAD 732 as required by paragraph 2 of that subdivision; provided, that the licensee is subject to the other provisions of that subdivision.

(4) Any licensee who is licensed pursuant to paragraph 1 for one or more of the medical use groups in Schedule C also is authorized subject to the provisions of this paragraph and paragraph 5, to receive, possess, and use for calibration and reference standards:

(a) Any radioactive material listed in Group I, Group II, or Group III of Schedule C to this chapter with a half-life not longer than one

hundred days, in amounts not to exceed fifteen millicuries total.

- (b) Any radioactive material listed in Group I, Group II, or Group III of Schedule C to this chapter with half-life greater than one hundred days in amounts not to exceed two hundred microcuries total.
- (c) Technetium-99m in amounts not to exceed thirty millicuries.
- (d) Any radioactive material, in amounts not to exceed three millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the department pursuant to subdivision a of subsection 5, a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.74, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

[1] A specific license issued by the department pursuant to subdivision a of subsection 5 or an application filed with the department pursuant to subdivision a of subsection 5 on or before July 1, 1977, for a license to manufacture and distribute a source that the applicant distributed commercially on or before July 1, 1977, on which application the department has not acted.

[2] A specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.74 or an application filed with the United States atomic energy commission pursuant to 10 CFR 32.74 on or before October 15, 1974, for a license to manufacture and distribute a source that the applicant distributed commercially on or before August 16, 1974, on which application the United States nuclear regulatory commission has not acted.

[3] A specific license issued by an agreement state pursuant to equivalent regulations or an application filed with an agreement state pursuant to equivalent regulations on or before July 1, 1977, for a license to

manufacture and distribute a source that the applicant distributed commercially on or before July 1, 1977, on which application the agreement state has not acted.

- (5) (a) Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to paragraph 4 shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source should not be used until tested, provided, however, that no leak tests are required when:

[1] The source contains one hundred microcuries or less of beta or gamma, or both, emitting material or ten microcuries or less of alpha emitting material; or

[2] The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date of use or transfer.

- (b) The leak test shall be capable of detecting the presence of five-thousandths microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department.

- (c) If the leak test reveals the presence of five-thousandths microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with this chapter and chapter 33-10-04. A report shall be filed within five days of the test with the department describing the equipment

involved, the test results, and the corrective action taken.

- (6) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to subparagraph d of paragraph 4 shall:
 - (a) Follow the radiation safety and handling instructions approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form.
 - (b) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.
- d. Human use of sealed sources. In addition to the requirements set forth in subsection 2, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user (1) has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and (2) is a physician.
- e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in subsection 2, a specific license for use of sealed sources in industrial radiography will be issued if all of the following are met:
 - (1) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the department a schedule or description of such program which specifies the:
 - (a) Initial training.
 - (b) Periodic training.
 - (c) On-the-job training.

- (d) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with ~~department regulations~~ this article and licensing requirements, and the operating and emergency procedures of the applicant.
 - (e) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant.
- (2) The applicant has established and submits to the department satisfactory written operating and emergency procedures described in subsection 2.
 - (3) ~~Management control shall begin upon becoming a licensee and a quarterly inspection shall be conducted thereafter to assure that license provisions, regulations, and operating and emergency procedures are being followed by radiographers and radiographers' assistants.~~ The applicant will have an internal inspection system adequate to ensure that this article, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections.
 - (4) The applicant submits to the department a description of the applicant's overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.
 - (5) The applicant who desires to conduct the applicant's own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the department a description of such procedures including:
 - (a) Instrumentation to be used.
 - (b) Method of performing tests, e.g., points on equipment to be smeared and method of taking smear.

(c) Pertinent experience of the person who will perform the test.

(6) The applicant will conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

4. **Special requirements for specific licenses of broad scope.** This subsection prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain ~~regulations~~ rules governing holders of such licenses. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States nuclear regulatory commission, Washington, D.C. 20555.)

a. The different types of broad licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Schedule D, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material

specified in Schedule D, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

- b. An application for a Type A specific license of broad scope will be approved if all of the following are met:
- (1) The applicant satisfies the general requirements specified in subsection 2.
 - (2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material.
 - (3) The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - (a) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material.
 - (b) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters.
 - (c) The establishment of appropriate administrative procedures to assure:
 - [1] Control of procurement and use of radioactive material.
 - [2] Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures.

[3] Review, approval, and recording by the radiation safety committee of safety evaluation of proposed uses prepared in accordance with item 2 of this subparagraph prior to use of the radioactive material.

c. An application for a Type B specific license of broad scope will be approved if all of the following are met:

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

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters.

(b) The establishment of appropriate administrative procedures to assure:

[1] Control of procurement and use of radioactive material.

[2] Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures.

[3] Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with item 2 of this subparagraph prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if all of the following are met:

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

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received all of the following:

- (a) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering.
 - (b) At least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.
- (3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting; and management review necessary to assure safe operations.
- e. Specific licenses of broad scope are subject to the following conditions:
- (1) Persons licensed pursuant to this subsection shall not:
 - (a) Conduct tracer studies in the environment involving direct release of radioactive material.
 - (b) Receive, acquire, own, possess, use, or transfer devices containing one hundred thousand curies or more of radioactive material in sealed sources used for irradiation of materials.
 - (c) Conduct activities for which a specific license issued by the department under subsection 3 or 5 is required.
 - (d) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.
 - (2) Each Type A specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
 - (3) Each Type B specific license of broad scope issued under this subsection shall be subject to the

condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of subdivision d.

5. Special requirements for specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.

a. Licensing the introduction of radioactive material into products in exempt concentrations. In addition to the requirements set forth in subsection 2, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under paragraph 1 of subdivision a of subsection 2 of section 33-10-03-02 will be issued if:

(1) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer.

(2) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(3) Each person licensed under this subsection shall file an annual report with the department which shall

identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of the radioactive material have been made pursuant to this division during the reporting period, the report shall so indicate. The report shall cover the year ending June thirtieth, and shall be filed within thirty days thereafter.

- b. Licensing the distribution of radioactive material in exempt quantities. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States nuclear regulatory commission, Washington, D.C. 20555.)
- (1) An application for a specific license to distribute ~~radioactive material other than source or byproduct material~~ NARM to persons exempted from ~~these regulations~~ this article pursuant to subdivision b of subsection 2 of section 33-10-03-02 will be approved if all of the following are met:
- (a) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.
 - (b) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.
 - (c) The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.

- (2) The license issued under paragraph 1 is subject to the following conditions:
- (a) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.
 - (b) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to subdivision b of subsection 2 of section 33-10-03-02. The outer package shall be such that the dose rate at the external surface of the package does not exceed one-half millirem per hour.
 - (c) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which (1) identifies the radionuclide and the quantity of radioactivity, and (2) bears the words "radioactive material".
 - (d) In addition to the labeling information required by subparagraph c, the label affixed to the immediate container, or an accompanying brochure, shall (1) state that the contents are exempt from United States nuclear regulatory commission or agreement state requirements or a licensing state; (2) bear the words "radioactive material - not for human use - introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited - exempt quantities should not be combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.
- (3) Each person licensed under this subdivision shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under subdivision b of subsection 2 of section 33-10-03-02 or the equivalent regulations of an agreement state or a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each

radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June thirtieth, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to this subdivision during the reporting period, the report shall so indicate.

- c. Licensing the incorporation of ~~radioactive material other than source or byproduct material~~ NARM into gas and aerosol detectors. An application for a specific license authorizing the incorporation of radioactive material other than source or byproduct material into gas and aerosol detectors to be distributed to persons exempt under paragraph 3 of subdivision c of subsection 2 of section 33-10-03-02 will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26 of the regulations of the United States nuclear regulatory commission. The maximum quantity of radium-226 in each device may not exceed one-tenth microcurie.
- d. Licensing the manufacture and distribution of devices to persons generally licensed under subdivision d of subsection 2 of section 33-10-03-04.
- (1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory commission, an agreement state, or a licensing state will be approved if:
- (a) The applicant satisfies the general requirements of subsection 2 of this section.
- (b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
- [1] The device can be safely operated by persons not having training in radiological protection.
- [2] Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or

inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of ten percent of the limits specified in the table of subdivision a of subsection 1 of section 33-10-04-02.

[3] Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

[a] Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye 15 rems

[b] Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter 200 rems

[c] Other organs 50 rems

(c) Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:

[1] Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).

[2] The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity.

[3] The information called for in One of the following statement in the same statements, as appropriate, or substantially similar form one:

[a] The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the United States nuclear regulatory commission, an agreement state, or a licensing state. (The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.) This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

(name of manufacturer or distributor)

[b] The receipt, possession, use, and transfer of the device Model _____, Serial No. _____, are subject to a general license or its equivalent and the regulations of a licensing state. (The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.) This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

(name of manufacturer or distributor)

- (2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval

for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

- (a) Primary containment (source capsule).
 - (b) Protection of primary containment.
 - (c) Method of sealing containment.
 - (d) Containment construction materials.
 - (e) Form of contained radioactive material.
 - (f) Maximum temperature withstood during prototype test.
 - (g) Maximum pressure withstood during prototype tests.
 - (h) Maximum quantity of contained radioactive material.
 - (i) Radiotoxicity of contained radioactive material.
 - (j) Operating experience with identical devices or similarly designed and constructed devices.
- (3) In the event the applicant desires that the general licensee under subdivision b of subsection 2 of section 33-10-03-04, or under equivalent regulations of the United States nuclear regulatory commission, an agreement state, or a licensing state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of ten percent of the limits specified in the table in subdivision a of subsection 1 of section 33-10-04-02.

- (4) Each person licensed under subdivision d to distribute devices to generally licensed persons shall:
- (a) Furnish a copy of the general license contained in subdivision b of subsection 2 of section 33-10-04-02 to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in subdivision b of subsection 2 of section 33-10-03-04.
 - (b) Furnish a copy of the general license contained in the United States nuclear regulatory commission, agreement state's, or licensing state's regulation equivalent to subdivision b of subsection 2 of section 33-10-03-04, or alternatively, furnish a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04 to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the United States nuclear regulatory commission, the agreement state, or the licensing state. If a copy of the general license in subdivision b of subsection 2 of section 33-10-03-04 is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the United States nuclear regulatory commission, agreement state, or a licensing state under requirements substantially the same as those in subdivision b of subsection 2 of section 33-10-03-04.
 - (c) Report to the department all transfers of such devices to persons for use under the general license in subdivision b of subsection 2 of section 33-10-03-04. Such report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and

relationship to the intended user. If no transfers have been made to persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04 during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within thirty days thereafter.

- (d) [1] Report to the United States nuclear regulatory commission all transfers of such devices to persons for use under the United States nuclear regulatory commission general license in 10 CFR 31.5.
- [2] Report to the responsible ~~agreement~~ state agency all transfers of such devices to persons for use under a general license in an agreement state's regulations equivalent to subdivision b of subsection 2 of section 33-10-03-04.
- [3] Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within thirty days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.
- [4] If no transfers have been made to United States nuclear regulatory commission licensees during the reporting period, this information shall be reported to the United States nuclear regulatory commission.
- [5] If no transfers have been made to a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of the department.

- (e) Keep records showing the name, address, and the point of contact for each general licensee to whom ~~he~~ the licensee directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in subdivision b of subsection 2 of section 33-10-03-04, or equivalent regulations of the United States nuclear regulatory commission or an agreement state or a licensing state. The records should show the date of each transfer, the isotope and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this section.
- e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under subdivision c of subsection 2 of section 33-10-03-04 will be approved subject to the following conditions:
- (1) The applicant satisfies the general requirements specified in subsection 2 of this section.
 - (2) The applicant satisfies the general requirements of 10 CFR 32.53, 32.54, 32.55, 32.56, and 32.101 or their equivalent.
- f. Special requirements for license to manufacture calibration sources containing americium-241, plutonium, or radium-226 for distribution to persons generally licensed under subdivision e of subsection 2 of section 33-10-03-04 will be approved subject to the following conditions:
- (1) The applicant satisfies the general requirement of subsection 2 of this section.
 - (2) The applicant satisfies the requirements of 10 CFR 32.57, 32.58, 32.59, and 32.102 and 10 CFR 70.39 or their equivalent.
- g. Manufacture and distribution of radioactive material for medical use under general license. In addition to requirements set forth in subsection 2, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in subdivision f of subsection 2 of section 33-10-03-04 will be issued if all of the following are met:

- (1) The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged in accordance with a new drug application which the commissioner of food and drugs, food and drug administration, has approved, or in accordance with a license for a biologic product issued by the secretary, United States department of health, education, and welfare.
- (2) ~~The~~ One of the following ~~statement~~ statements, as appropriate, or a substantially similar statement which contains the information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:
 - (a) This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to ~~the regulations~~ this article and a general license or its equivalent of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

- (b) This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of medicine. Its receipt, possession, use, and transfer are subject to ~~the regulations~~ this article and a general license or its equivalent of a licensing state.

Name of manufacturer

- h. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of subdivision g of subsection 2 of section 33-10-03-04 will be approved if:
 - (1) The applicant satisfies the general requirements specified in subsection 2 of this section.
 - (2) The radioactive material is to be prepared for distribution in prepackaged units of:

- (a) Iodine-125 in units not exceeding ten microcuries each.
 - (b) Iodine-131 in units not exceeding ten microcuries each.
 - (c) Carbon-14 in units not exceeding ten microcuries each.
 - (d) Hydrogen-3 (tritium) in units not exceeding fifty microcuries each.
 - (e) Iron-59 in units not exceeding twenty microcuries each.
 - (f) Cobalt-57 in units not exceeding ten microcuries each.
 - (g) Selenium-75 in units not exceeding ten microcuries each.
 - (h) Mock iodine-125 in units not exceeding five-hundredths microcurie of iodine-129 and five-thousandths microcurie of americium-241 each.
- (3) Each prepackaged unit bears a durable, clearly visible label:
- (a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; fifty microcuries of hydrogen-3 (tritium); or twenty microcuries of iron-59 or mock iodine-125 in units not exceeding five-hundredths microcurie of iodine-129 and five-thousandths microcurie of americium-241 each.
 - (b) Displaying the radiation caution symbol described in paragraph 1 of subdivision a of subsection 3 of section 33-10-04-03 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".
- (4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- (a) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations this article and a general license of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

- (b) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations this article and a general license of a licensing state.

Name of manufacturer

- (5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material.
- i. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under subdivision h of subsection 2 of section 33-10-03-04 will be approved subject to the following conditions: (1) the applicant satisfies the general requirements of subsection 2 of this section and, (2) the criteria of 10 CFR 32.61, 32.62, and 32.103 are met.
- j. Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses.

(1) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to subdivision c of subsection 3 for the uses listed in Group I, Group II, Group IV, or Group V of Schedule C to this chapter will be approved if:

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

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

(a) [1] The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packed 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; a ~~biologic product license issued by the 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) [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.

(3) (c) 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 which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees.

(4) (a) (d) [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 subdivision c of subsection 3 Schedule C Group I, Group II, Group IV, and Group V of chapter 33-10-03, as appropriate, or under equivalent licenses of the United States

nuclear regulatory commission, an agreement state, or a licensing state.

(b) [2] The labels, leaflets, or brochures required by this subdivision 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.

k. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material.

(1) 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 subdivision c of subsection 3 for the uses listed in Group III of Schedule C of this chapter will be approved if:

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

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

(a) [1] 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, a biologic product license issued 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) [2] 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) (c) 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→ (d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay.

←5→ (e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

←a→ [1] Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit.

←b→ [2] A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the department pursuant to subdivision c of subsection 3 of section 33-10-03-05 and Schedule C Group III of chapter 33-10-03 or under equivalent licenses of the United States nuclear regulatory commission, an agreement state, or a licensing state. The labels, leaflets, or brochures required by this subdivision 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.

Note: Although the department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have the reagent kits approved by the department for use by persons licensed pursuant to subdivision c of subsection 3 of section 33-10-03-05 and Group III of Schedule C may submit the pertinent information specified in this subdivision to this chapter.

1. Manufacture and distribution of sources or devices containing radioactive material for medical use.

- (1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to subdivision c of subsection 3 for use as a calibration or reference source or for the uses listed in Group VI of Schedule C to this chapter will be approved if:
 - (a) The applicant satisfies the general requirements in subsection 2.
 - (b) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - [1] The radioactive material contained, its chemical and physical form, and amount.
 - [2] Details of design and construction of the source or device.
 - [3] Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accident.
 - [4] For devices containing radioactive material, the radiation profile of a prototype device.
 - [5] Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests.
 - [6] Procedures and standards for calibrating sources and devices.
 - [7] Legend and methods for labeling sources and devices as to their radioactive content.
 - [8] Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail in a brochure which is referenced on the label.

- (c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the (name of source or device) is licensed by the department for distribution to persons licensed pursuant to subdivision c of subsection 3 and Schedule C Group VI to this chapter or under equivalent licenses of the United States nuclear regulatory commission, an agreement state, or a licensing state; provided, that such labeling for sources which do not require long-term storage, e.g., gold-198 seeds, may be on a leaflet or brochure which accompanies the source.
- (2) (a) If the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.
- (b) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes, but is not limited to:
- [1] Primary containment (source capsule).
 - [2] Protection of primary containment.
 - [3] Method of sealing containment.
 - [4] Containment construction materials.
 - [5] Form of contained radioactive material.
 - [6] Maximum temperature withstood during prototype tests.
 - [7] Maximum pressure withstood during prototype tests.
 - [8] Maximum quantity of contained radioactive material.

- [9] Radiotoxicity of contained radioactive material.
 - [10] Operating experience with identical sources or devices or similarly designed and constructed sources or devices.
- m. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.
- (1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to subdivision e of subsection 1 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:
 - (a) The applicant satisfies the general requirements specified in subsection 2 of this section.
 - (b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in subsection 1 of section 33-10-04-02.
 - (c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
 - (2) In the case of an industrial product or device whose unique benefits are questionable, the department will approve an application for a specific license under this subdivision only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
 - (3) The department may deny any application for a specific license under this subdivision if the end

uses of the industrial product or device cannot be reasonably foreseen.

- (4) Each person licensed pursuant to paragraph 1 shall:
- (a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device.
 - (b) Label or mark each unit to:
 - [1] Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
 - [2] State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the United States nuclear regulatory commission or of an agreement state.
 - (c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium".
 - (d)
 - [1] Furnish a copy of the general license contained in subdivision e of subsection 1 of section 33-10-03-04 and a copy of department Form RAD 811 to each person to whom the person licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in subdivision e of subsection 1 of section 33-10-03-04; or
 - [2] Furnish a copy of the general license contained in the United States nuclear regulatory commission's or agreement state's regulation equivalent to subdivision e of subsection 1 of section 33-10-03-04 and a copy of the United States nuclear regulatory commission's or agreement state's certificate, or alternatively, furnish a copy of the

general license contained in subdivision e of subsection 1 of section 33-10-03-04 and a copy of the general license to each person to whom the person licensee transfers depleted uranium in a product or device for use pursuant to the general license of the United State United States nuclear regulatory commission or an agreement state, with a note explaining that use of the product or device is regulated by the United States nuclear regulatory commission or an agreement state under requirements substantially the same as those in subdivision e of subsection 1 of section 33-10-03-04.

- (e) Report to the department all transfers of industrial products or devices to persons for use under the general licensee by name and address, an individual by name and position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under subdivision e of subsection 1 of section 33-10-03-04 during the reporting period, the report shall so indicate.
- (f) [1] Report to the United States nuclear regulatory commission all transfers of industrial products or devices to persons for use under the United States nuclear regulatory commission general license in 10 CFR 40.25.
- [2] Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subdivision for use under a general license in that state's regulations equivalent to subdivision e of subsection 1 of section 33-10-03-04.
- [3] Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the department and

the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

[4] If no transfers have been made to United States nuclear regulatory commission licensees during the reporting period, this information shall be reported to the United States nuclear regulatory commission.

[5] If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency.

(g) Keep records showing the name, address, and point of contact for each general licensee to whom the person licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in subdivision e of subsection 1 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory commission or of an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

n. Special requirements for issuance of specific licenses for source material milling. In addition to the requirements set forth in subsection 2, a specific license for source material milling will be issued if the applicant submits to the department a satisfactory application as described herein and meets the other conditions specified below:

(1) An application for a license to receive title to, receive, possess, and use source material for milling or byproduct material as defined in subdivision b of subsection 6 shall address the following:

(a) Description of the proposed project or action.

(b) Area/site characteristics including geology, topography, hydrology, and meteorology.

- (c) Radiological and nonradiological impacts of the proposed project or action, including waterway and ground water impacts.
 - (d) Environmental effects of accidents.
 - (e) Tailings disposal and decommissioning
Long-term impacts including decommissioning,
decontamination, and reclamation.
 - (f) Site and project alternatives.
- (2) Pursuant to subdivision e of subsection 2 the applicant may not commence construction of the project until the department has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.
 - (3) At least one full year prior to any major site construction, a preoperational monitoring program shall 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 shall be conducted to measure or evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.
 - (4) Prior to issuance of the license, the mill operator shall establish financial surety arrangements consistent with the requirements of subdivision f of subsection 2.
 - (a) The amount of funds to be ensured by financial surety arrangements shall be based on department-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. 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 that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall 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 surety arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that 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 are clearly identified. The licensee's surety mechanism will be reviewed annually by the department to assure that sufficient funds will 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 shall 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, decontamination, 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 could be provided with a surety instrument which is written for a specified period of time, e.g., five years, which must be automatically renewed unless the surety agent notifies the beneficiary (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.

- (b) The total amount of funds for reclamation or long-term surveillance and control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long-term surveillance and control. Such funds do not, however, include moneys held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.
- (5) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.
- (a) Milling operations shall be conducted so that all effluent releases are reduced to as low as is reasonably achievable below the limits of chapter 33-10-04.
- (b) The mill operator shall conduct daily inspection of any tailings or waste retention systems. Records of such inspections shall be maintained for review by the department.
- (c) The mill operator shall immediately notify the department of the following:
- [1] Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas.
- [2] Any unusual conditions (conditions not contemplated in the design of the retention system) which if not corrected could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.
- (6) Continued surveillance requirements for source material mills having reclaimed residues.
- (a) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of

the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection shall be reported to the United States nuclear regulatory commission within sixty days following each inspection. The United States nuclear regulatory commission may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

(b) A minimum charge of two hundred fifty thousand dollars in 1978 dollars to cover the costs of long-term surveillance shall be paid by each mill operator to the department 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 subparagraph a, additional funding requirements may be specified by the department. The total charge to cover the costs of long-term surveillance shall 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 charge will be reviewed annually to recognize or adjust for inflation.

(7) An application for a license to own, receive, possess, and use byproduct material as defined in subsection 6 of section 33-10-01-04 shall contain proposed specifications relating to the emissions control and disposition of the byproduct material to achieve the requirements and objectives set forth in the criteria listed in Schedule E of chapter 33-10-03.

6. Issuance of specific licenses.

- a. Upon a determination that an application meets the requirements of North Dakota Century Code chapter 23-20.1 and this chapter, the department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- b. The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, ~~regulation,~~ or order, such additional requirements and

conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

- (1) Minimize danger to public health and safety or property.
- (2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary.
- (3) Prevent loss or theft of material subject to this chapter.

7. Specific terms and conditions of licenses.

- a. Each license issued pursuant to this chapter shall be subject to all the provisions of North Dakota Century Code chapter 23-20.1 and to all applicable rules, ~~regulations~~, and orders of the department.
 - b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information find that the transfer is in accordance with the provisions of North Dakota Century Code chapter 23-20.1, and shall give its consent in writing.
 - c. Each person licensed by the department pursuant to this chapter shall confine the person's use and possession of the material licensed to the locations and purposes authorized in the license.
 - d. Each licensee shall notify the department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.
- 8. Expiration of licenses.** 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.
- 9. Renewal of licenses.**
- a. Applications for renewal of specific licenses shall be filed in accordance with subsection 1.

- b. In any case in which a licensee, not less than thirty days prior to expiration of the licensee's existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the department.
10. **Amendment of licenses at request of licensee.** Applications for amendment of a license shall be filed in accordance with subsection 1 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.
11. **Department action on applications to renew or amend.** In considering an application by a licensee to renew or amend the license, the department will apply the criteria set forth in subsection 2, 3, 4, or 5 as applicable.
12. Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass. Any person who, on June 1, 1986, possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the United States nuclear regulatory commission, shall be deemed to possess a like license issued under this article, such license to expire either ninety days after receipt from the department of a notice of expiration of such license, or on the date of expiration specified in the United States nuclear regulatory commission license, whichever is earlier.
13. Persons possessing naturally occurring and accelerator-produced radioactive material. Any person who, on June 1, 1986, possesses NARM for which a specific license is required by the article shall be deemed to possess such a license issued under the article. Such license shall expire ninety days after the effective date of these rules; provided, however, that if within the ninety days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the department.
14. **Transfer of material.**
- a. No licensee shall transfer radioactive material except as authorized pursuant to this subsection.
- b. Except as otherwise provided in one's license and subject to the provisions of subdivisions c and d, any licensee may transfer radioactive material:

- (1) To the department. (A licensee may transfer material to the department only after receiving prior approval from the department.)
 - (2) To the United States department of energy.
 - (3) To any person exempt from ~~the regulations in~~ this chapter to the extent permitted under such exemption.
 - (4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States nuclear regulatory commission, any agreement state, or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the department, any agreement state, or licensing state.
 - (5) As otherwise authorized by the department in writing.
- c. Before transferring radioactive material to a specific licensee of the department, the United States nuclear regulatory commission, an agreement state, or licensing state, or to a general licensee who is required to register with the department, the United States nuclear regulatory commission, an agreement state, or licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.
- d. The following methods for the verification required by subdivision c are acceptable:
- (1) The transferor may have in the transferor's possession, and read, a current copy of the transferee's specific license or registration certificate.
 - (2) The transferor may have in the transferor's possession a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.
 - (3) For emergency shipments the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration

certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed, in writing, within ten days.

- (4) The transferor may obtain other sources of information compiled by a reporting service from official records of the department, the United States nuclear regulatory commission, or the licensing agency of an agreement state, or a licensing state as to the identity of licensees and the scope and expiration dates of licenses and registration.
 - (5) When none of the methods of verification described in paragraphs 1 and 4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the United States nuclear regulatory commission, or the licensing agency of an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.
- e. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of section 33-10-03-07.

~~±3-~~ 15. Modification, revocation, and termination of licenses.

- a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to North Dakota Century Code chapter 23-20.1, or by reason of ~~rules, regulations~~ this article, and orders issued by the department.
- b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of North Dakota Century Code chapter 23-20.1, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of North Dakota Century Code chapter 23-20.1, or of the license, or of ~~any rule, regulation~~ this article, or any order of the department.

- c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee, in writing, and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.
- d. The department may terminate a specific license upon request submitted by the licensee to the department in writing.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 23-20.1-04

33-10-03-06. Reciprocity.

~~1- Licenses of byproduct, source, and special nuclear material in quantities not sufficient to form a critical mass-~~

a- 1. Subject to this chapter, any person who holds a specific license from the United States nuclear regulatory commission or any agreement state, or any licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period ~~not~~ in excess of one hundred eighty days in any calendar year of one year beginning with the date of notification provided that:

~~(1)~~ a. The licensing document does not limit the activity authorized by such document to specified installations or locations.

~~(2)~~ b. The out-of-state licensee notifies the department, in writing, at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document and a copy of the licensee's operating and procedures manual. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of

the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

~~(3)~~ c. The out-of-state licensee complies with ~~all applicable regulations of the department~~ this article and with all the terms and conditions of the licensee's licensing document, except any such terms and conditions which may be inconsistent with ~~applicable regulations of the department~~ this article.

~~(4)~~ d. The out-of-state licensee supplies such other information as the department may request.

~~(5)~~ e. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person:

~~(a)~~ (1) Specifically licensed by the department or the United States nuclear regulatory commission, another licensing state, or an agreement state to receive such material; or

~~(b)~~ (2) Exempt from the requirements for a license for such material under subdivision a of subsection 2 of section 33-10-03-02, or subsection 2 of this section.

f. The out-of-state licensee shall submit an annual fee of three hundred dollars at the time of written notification.

~~b-~~ 2. Notwithstanding the provisions of subsection 1, any person who holds a specific license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in paragraph 1 of subdivision d of subsection 2 of section 33-10-03-04 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

~~(1)~~ a. The person shall file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device.

~~(2)~~ b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the United States

nuclear regulatory commission ~~or~~, an agreement state, or
a licensing state.

(3) c. The person shall ~~assure~~ ensure that any labels required to be affixed to the device under regulations requirements of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited".

(4) d. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in subdivision d of subsection 2 of section 33-10-03-04.

e- 3. The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency the United States nuclear regulatory commission, an agreement state, or licensing state, or of any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

**2- Licenses of naturally occurring and
accelerator-produced radioactive material-**

a- Subject to this chapter, any person who holds a specific license from the United States nuclear regulatory commission or any licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty days in any calendar year provided that-

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations-

(2) The out-of-state licensee notifies the department in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an

undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

- (3) The out-of-state licensee complies with all applicable regulations of the department and with all terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the department.
- (4) The out-of-state licensee supplies such other information as the department may request.
- (5) The out-of-state licensee may not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person:

- (a) Specifically licensed by the department or by the United States nuclear regulatory commission or another licensing state to receive such material; or

- (b) Exempt from the requirements for a license for such material under this subsection.

b- Notwithstanding the provisions of this subsection, any person who holds a specific license issued by the United States nuclear regulatory commission, a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in paragraph 1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

- (1) Such person shall file a report with the department within thirty days after the end

of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device.

- (2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the United States nuclear regulatory commission or a licensing state.
 - (3) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "removal of this label is prohibited".
 - (4) The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in this subdivision.
- e- The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-03-07. Transportation.

1. No person may deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general or specific license issued by the department or as exempted in the following:
 - a. Common and contract carriers, freight forwarders, and warehousemen who are subject to the rules and regulations of the United States department of transportation in 49

CFR 170 through 189 or the United States postal service in the postal service manual (domestic mail manual), section 124.3 incorporated by reference, 39 CFR 111.11 (1974) are exempt from this article to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common and contract carriers who are not subject to the rules and regulations of the United States department of transportation or United States postal service are subject to ~~6-100~~ this section and other applicable sections of this article.

- b. Physicians, as defined in section 33-10-01-04, are exempt from the requirements of subsection 1 to the extent that they transport radioactive material for use in the practice of medicine.
- c. Any licensee is exempt from subsection 1 to the extent that the licensee delivers to a carrier for transport packages each of which contains no radioactive material having a specific activity in excess of two-thousandths microcurie per gram.
- d. Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the United States postal service, is exempt from the provisions of subsection 1.

2. Intrastate transport.

- a. A general license is hereby issued to any common or contract carrier to receive, possess, transport, and store radioactive material in the regular course of carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the United States department of transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. (Any notification of incidents referred to in these requirements shall be filed with, or made to, the department.)
- b. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the United States department of transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. (Any notification of incidents referred to in these

requirements shall be filed with, or made to, the department.)

- c. Persons who transport radioactive material pursuant to the general licenses in subdivision a or b are exempt from the requirements of chapters 33-10-04 and 33-10-10 to the extent that they transport radioactive material.
3. Preparation of radioactive material for transport. A general license is hereby issued to deliver radioactive material to a carrier for transport provided that:
 - a. The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the United States department of transportation insofar as such regulations relate to the packaging of radioactive material, and to the monitoring, marking, and labeling of those packages.
 - b. The licensee has established procedures for opening and closing packages, in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is closed for transport.
 - c. Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee. (For the purpose of this section, a licensee who transports one's own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.)
 4. Advance notification of transport of nuclear waste. For the purpose of this section "nuclear waste" means any large quantity of source, byproduct, or special nuclear material required to be in Type B packaging while transported to, through or across state boundaries to a disposal site, or to a collection point for transport to a disposal site.
 - a. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor (or governor's designee) of each state through which the waste will be transported.
 - b. Each advance notification required by subdivision a must contain the following information:
 - (1) The name, address, and telephone number of the shipper, carrier, and receiver of the shipment.

- (2) A description of the nuclear waste contained in the shipment as required by the regulations of the United States department of transportation in 49 CFR 172.202 and 172.203(d).
 - (3) The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur.
 - (4) The seven-day period during which arrival of the shipment at state boundaries is estimated to occur.
 - (5) The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur.
 - (6) A point of contact with a telephone number for current shipment information.
- c. The notification required by subdivision a shall be made in writing to the office of each appropriate governor (or governor's designee) and to the department. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor (or governor's designee) at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.
- d. The licensee shall notify each appropriate governor (or governor's designee) and the department of any changes to schedule information provided pursuant to subdivision a. Such notification shall be by telephone to a responsible individual in the office of the governor (or governor's designee) of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.
- e. Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor (or governor's designee) of each appropriate state and to the department. A copy of the notice shall be retained by the licensee for one year.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-04-02. Permissible doses, levels, and concentrations.

1. Radiation dose standards to individuals in restricted areas. (For determining the doses specified in subdivision a of this subsection a dose from x or gamma rays up to ten megaelectronvolts MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.)

a. In accordance with subdivision a of subsection 2 and except as provided in subdivision b, no licensee or registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation a total occupational dose in excess of the standards specified in the following table:

	<u>Rems per Calendar Quarter</u>
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	1 1/4
Hands and forearms; feet and ankles	18 3/4
Skin of whole body	7 1/2

b. A licensee or registrant may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under subdivision a, provided all of the following:

- (1) During any calendar quarter the total occupational dose to the whole body shall not exceed three rems.
- (2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rems where "N" equals the individual's age in years at the individual's last birthday.
- (3) The licensee or registrant has determined the individual's accumulated occupational dose to the whole body on Department Form RAD 682 or on a clear and legible record containing all the information required in that form and has otherwise complied with the requirements of subsection 2. As used in this subdivision, "dose to the whole body" includes any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of eye.

2. Determination of accumulated dose.

- a. Each licensee or registrant shall require any individual, prior to first entry of the individual into the licensee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of twenty-five percent of the applicable standards specified in this subdivision and subsection 4, to disclose in a written, signed statement, either (1) that the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during the specifically identified current calendar quarter from sources of radiation possessed or controlled by other persons. Each licensee or registrant shall maintain records of such statements until the department authorizes their disposition.
- b. Before permitting, pursuant to subdivision b of subsection 1 of this section, any individual in a restricted area to be exposed to receive an occupational radiation dose in excess of the limits standards specified in subdivision a of subsection 1, each licensee or registrant shall:
 - (1) Obtain a certificate on Department Form RAD 682 or on a clear and legible record containing all the information required in that form, signed by the individual, showing each period of time after the individual attained the age of eighteen in which the individual received an occupational dose of radiation.
 - (2) Calculate on Department Form RAD 682 in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under subdivision b of subsection 1.
- c. (1) In the preparation of Department Form RAD 682, or a clear and legible record containing all the information required in that form, the licensee or registrant shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee or registrant obtains such reports, the licensee or registrant shall use the dose shown in the report in preparing the form. In any case where a licensee or registrant is unable to obtain reports

of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns apply:

Part of Body	Column 1 Assumed Dose in Rems for Calendar Quarters Prior to January 1, 1961	Column 2 Assumed Dose in Rems for Calendar Quarters Beginning on or After January 1, 1961
Whole body, gonads, active blood-forming organs, head and trunk, lens of eye	3 3/4	1 1/4

- (2) The licensee or registrant shall retain and preserve records used in preparing Department Form RAD 682 until the department authorizes their disposition. If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in paragraph 2 of subdivision b of subsection 1, the excess may be disregarded.
3. Exposure of individuals to concentrations of radioactive material in restricted areas.
- a. No licensee shall possess, use, or transfer radioactive material in such a manner as to permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity which would result from inhalation for forty hours per week for thirteen weeks at uniform concentrations of radioactive material in air specified in Appendix A, Table I, of this chapter. If the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake in any calendar quarter does not exceed that which would result from inhaling such radioactive material for forty hours per week or thirteen weeks at uniform concentrations specified in Appendix A.

Since the concentration specified for tritium oxide vapor assumes equal intakes by skin absorption and inhalation, the total intake permitted is twice that which would

result from inhalation alone at the concentration specified for H-3(S) in Appendix A, Table I, of this chapter for forty hours per week for thirteen weeks.

For radon-222, the limiting quantity is that inhaled in a period of one calendar year. For radioactive material designated "Sub" in the "Isotope" column of the table, the concentration value specified is based upon exposure to the material as an external radiation source. Individual exposures to these materials may be accounted for as part of the limitation on individual dose in chapter 33-10-04. These nuclides shall be subject to the precautionary procedures required by this chapter.

Multiply the concentration values specified in Appendix A of this chapter by 6.3×10^8 ml to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix A of this chapter by 2.5×10^9 ml to obtain the annual quantity limit for Rn-222.

- b. To determine compliance with subdivision a:
- (1) The concentration for soluble hydrogen 3 in Table I, Column 1, of this chapter may be multiplied by 2.
 - (2) For radon-222, a limiting quantity is that inhaled in a period of one calendar year.
 - (3) For radioactive material designated "Sub" in the "Isotope" column of Table I of this chapter, the specified concentrations are based upon exposure to the radioactive material as an external source; hence, individual exposures to these radioactive materials may be accounted for as part of the limitation on individual dose in one point of this section.
 - (4) It shall be assumed that a person working forty hours per week inhales 6.3×10^8 ml of air during thirteen such weeks and 2.5×10^9 ml of air during one year.
- c. Notwithstanding subdivision a, if radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake in any calendar quarter does not exceed that which would result from inhaling such radioactive material for forty hours per week for thirteen weeks at uniform concentrations specified in Appendix A, Table I, Column 1, of this chapter.

- d. No licensee shall possess, use, or transfer mixtures of U-234, U-235, and U-238 in soluble form in such a manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix A, Table I, Column 1, of this chapter. If such soluble uranium is of a form such that absorption through the skin is likely, individual exposures to such material shall be controlled so that the uptake of such material by any organ from either inhalation or absorption or both routes of intake does not exceed that which would result from inhaling such material at the limit specified in Appendix A, Table I, Column 1, of this chapter. (Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in subsection 1 has been exceeded.)
- e. For the purpose of determining compliance with the requirements of this section, the licensee shall use suitable measurements of concentrations of radioactive materials in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body, or any combination of such measurements as may be necessary for detection and assessment of individual intakes of radioactivity by exposed individuals. It is assumed that an individual inhales radioactive material at the airborne concentration in which he an individual is present unless he the individual uses respiratory protective equipment pursuant to this subsection. When assessment of a particular individual's intake of radioactive material is necessary, intakes less than those which would result from inhalation for two hours in any one day or for ten hours in any one week at uniform concentrations specified in Appendix A, Table I, Column 1, of this chapter need not be included in such assessment, provided that for any assessment in excess of these amounts the entire amount is included.
- f. The licensee shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area as defined in subdivision d of subsection 3 of section 33-10-04-03. When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material

in air below those defined in subdivision d of subsection 3 of section 33-10-04-03, other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material by any individual within any period of seven consecutive days as far below that intake of radioactive material which would result from inhalation of such material for forty hours at the uniform concentrations specified in Appendix A, Table I, Column 1, of this chapter as is reasonably achievable. Whenever the intake of radioactive material by any individual exceeds this forty hour control measure, the licensee shall make such evaluations and take such actions as are necessary to assure against reoccurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

- g. When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to subdivision f, a licensee may make allowance for such use in estimating exposures of individuals to such materials provided that such equipment is used as stipulated in regulatory guide 8.15, "Acceptable Programs for Respiratory Protection", of the United States nuclear regulatory commission.
- h. Notwithstanding the provisions of subdivisions f and g, the department may impose further restrictions:
 - (1) On the extent to which a licensee may make allowance for use of respirators in lieu of provision of process, containment, ventilation, or other engineering controls, if application of such controls is found to be practicable; and
 - (2) As might be necessary to assure that the respiratory protective program of the licensee is adequate in limiting exposures of personnel to airborne radioactive materials.
- i. The licensee shall notify, in writing, the department at least thirty days before the date that respiratory equipment is first used under the provisions of this subsection.
- j. A licensee who was authorized to make allowance for use of respiratory protective equipment prior to ~~(the effective date of this section)~~ October 1, 1982, shall bring the licensee's respiratory protective program into conformance with the requirements of subdivision g

within one year of that date, and is exempt from the requirements of subdivision e.

4. Exposure of minors. (For determining the doses specified in this subsection, a dose from x or gamma rays up to ten MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.)
 - a. No licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual within a restricted area, who is under eighteen years of age, to receive in any period of one calendar quarter from all sources of radiation in such licensee's or registrant's possession a dose in excess of ten percent of the limits specified in the table in subdivision a of subsection 1.
 - b. No licensee shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under eighteen years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix A, Table II, of this chapter. For purposes of this subdivision, concentrations may be averaged over periods not greater than a week.
 - c. The provisions of subdivision c of subsection 3 shall apply to exposures subject to subdivision b.
5. Permissible levels of radiation from external sources in unrestricted areas. (It is the intent of this subsection to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of one-half rem in any one year. If in specific instances, it is determined by the department that this intent is not met, the department may, pursuant to section 33-10-01-09, impose such additional requirements on the licensee or registrant as may be necessary to meet the intent.)
 - a. Except as authorized by the department pursuant to subdivision b, no licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to create in any unrestricted area from such sources of radiation in the licensee's or registrant's possession:
 - (1) Radiation levels which, if an individual were continuously present in the area, could result in the individual receiving a dose in excess of two millirems in any one hour; or

- (2) Radiation levels which, if an individual were continuously present in the area, could result in the individuals receiving a dose in excess of one hundred millirems in any seven consecutive days.
 - b. Any person may apply to the department for proposed limits upon levels of radiation in unrestricted areas in excess of those specified in subdivision a resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The department will approve the proposed limits if the applicant demonstrates to the satisfaction of the department that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of one-half rem.
6. Concentration of radioactivity in effluents to unrestricted areas.
- a. A licensee shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix A, Table II, of this chapter, except as authorized pursuant to subsection 2 of section 33-10-04-04 or subdivision b of this subsection. For purposes of this subsection concentrations may be averaged over a period not greater than one year.
 - b. An application for a license or amendment may include proposed limits higher than those specified in subdivision a. The department will approve the proposed limits if the applicant demonstrates all of the following:
 - (1) That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas.
 - (2) That it is not likely that radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits specified in Appendix A, Table II, of this chapter.
 - c. An application for higher limits pursuant to subdivision b shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to unrestricted areas, and shall include, as pertinent:

- (1) Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent, and concentration of each radionuclide in the effluent averaged over a period of one year at the point where the effluent leaves a stack, tube, pipe, or similar conduit.
- (2) A description of the properties of the effluents, including:
 - (a) Chemical composition.
 - (b) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents.
 - (c) The hydrogen ion concentrations (~~pH~~) (pH) of liquid effluents.
 - (d) The size range of particulates in effluents released into air.
- (3) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent.
- (4) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of one year:
 - (a) In air at any point of human occupancy; or
 - (b) In water at points of use downstream from the point of release of the effluent.
- (5) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent.
- (6) A description of the environmental monitoring equipment, including sensitivity of the system, and procedures and calculations to determine concentrations of radionuclides in the unrestricted area and possible reconcentrations of radionuclides.
- (7) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.

- d. For the purposes of this subsection, the concentration limits in Appendix A, Table II, of this chapter shall apply at the boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe, or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.
 - e. In addition to limiting concentrations in effluent streams, the department may limit quantities of radioactive material released in air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water, or food by a suitable sample of an exposed population group, averaged over a period not exceeding one year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing one-third the concentration of radioactive material specified in Appendix A, Table II, of this chapter.
 - f. The provisions of this subsection do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by subsection 3 of section 33-10-04-04.
7. Orders requiring furnishing of bioassay services. Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the department may incorporate license provisions or issue an order requiring a licensee or registrant to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the department.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 23-01-03

33-10-04-03. Precautionary procedures.

- 1. Surveys. Each licensee or registrant shall make or cause to be made such surveys as may be necessary for the applicant to establish compliance with this chapter.
- 2. Personnel monitoring. Each licensee or registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by:
 - a. Each individual who enters a restricted area under such circumstances that the individual receives, or is likely

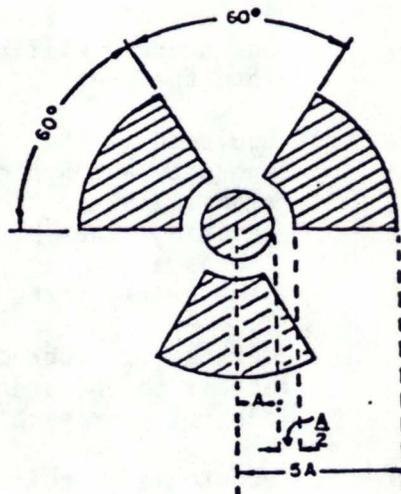
to receive, a dose in any calendar quarter in excess of twenty-five percent of the applicable value specified in subdivision a of subsection 1 of section 33-10-04-02.

- b. Each individual under eighteen years of age who enters a restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter in excess of five percent of the applicable value specified in subdivision a of subsection 1 of section 33-10-04-02.
 - c. Each individual who enters a high radiation area.
3. Caution signs, labels, and signals.
- a. General.

- (1) Except as otherwise authorized by the department, symbols prescribed by this subsection shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this subsection is the conventional three blade design:

RADIATION SYMBOL

- (a) Crosshatch area is to be magenta or purple.
- (b) Background is to be yellow.



- (2) In addition to the contents of signs and labels prescribed in this subsection, a licensee or registrant may provide on or near such signs and

labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.

- b. Radiation areas. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION*

RADIATION AREA

*or "DANGER"

- c. High radiation areas.

- (1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION*

HIGH RADIATION AREA

*or "DANGER"

- (2) Each entrance or access point to a high radiation area shall be:
- (a) Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of one hundred millirems in one hour upon entry into the area;
 - (b) Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the licensee or a supervisor of the activity are made aware of the entry; or
 - (c) Maintained locked except during periods when access to the area is required, with positive control over each individual entry.
- (3) The controls required by paragraph 2 shall be established in such a way that no individual will be prevented from leaving a high radiation area.
- (4) In the case of a high radiation area established for a period of thirty days or less, direct surveillance

to prevent unauthorized entry may be substituted for the controls required by paragraph 2.

(5) Any licensee or registrant may apply to the department for approval of methods not included in paragraphs 2 and 4 for controlling access to high radiation areas. The department will approve the proposed alternatives if the licensee or registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of paragraph 3 is met.

(6) Each area in which there may exist radiation levels in excess of five hundred rems in one hour at one meter from a sealed radioactive source that is used to irradiate materials shall have entry control devices and alarms meeting the criteria specified in 10 CFR 20.203(c)(6).

(7) The requirements of paragraph 6 of this subdivision shall not apply to radioactive sources that are used in teletherapy, industrial radiography, or in completely self-contained irradiators. In the case of open field irradiators in which certain of the criteria specified in paragraph 6 are impracticable, equivalent protection shall be provided by license conditions.

d. Airborne radioactivity areas. Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION*

AIRBORNE RADIOACTIVITY AREA

*or "DANGER"

e. Additional requirements.

(1) Each area or room in which any radioactive material, other than natural uranium or thorium, is used or stored in an amount exceeding ten times the quantity of radioactive material specified in Appendix B of this chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION*

RADIOACTIVE MATERIAL

*or "DANGER"

- (2) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding one hundred times the quantity specified in Appendix B of this chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION*

RADIOACTIVE MATERIAL

*or "DANGER"

f. Containers.

- (1) Except as provided in paragraph 3, each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents.
- (2) A label required pursuant to paragraph 1 shall bear the radiation caution symbol and the words:

CAUTION*

RADIOACTIVE MATERIAL

*or "DANGER"

It shall also provide sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures. (As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, etc.)

- (3) Notwithstanding the provisions of paragraph 1, labeling is not required:
 - (a) For containers that do not contain radioactive material in quantities greater than the applicable quantities listed in Appendix B of this chapter.
 - (b) For containers containing only natural uranium or thorium in quantities no greater than ten

times the applicable quantities listed in Appendix B of this chapter.

- (c) For containers that do not contain radioactive material in concentrations greater than the applicable concentrations listed in Column 2, Table I, Appendix A of this chapter.
 - (d) For containers **when they are** attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established by this chapter.
 - (e) For containers **when they are** in transport and packaged and labeled in accordance with regulations published by the department of transportation.
 - (f) For containers **which are** accessible only to individuals authorized to handle or use them or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record. (For example, containers in locations such as water-filled canals, storage vaults, or hot cells.)
 - (g) For manufacturing and process equipment such as piping and tanks.
- (4) Each license shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- g. All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.
4. Exceptions from posting and labeling requirements. Notwithstanding the provisions of subdivision c of subsection 3:
- a. A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level twelve inches [30.5 centimeters], from the surface of the source container or housing does not exceed five millirem per hour.
 - b. Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to subdivision c of subsection 3

is not required, because of the presence of patients containing radioactive material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the regulations in this chapter.

- c. Caution signs are not required to be posted in areas or rooms containing radioactive material for periods of less than eight hours provided that (1) the material is constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in this part, and (2) such area or room is subject to the licensee's or registrant's control.
 - d. A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the department of transportation.
5. Instruction of personnel. Instructions required for individuals working in or frequenting any portion of a restricted area are specified in subsection 2 of section 33-10-10-01.
 6. Storage and control of sources of radiation.
 - a. Sources of radiation shall be secured from unauthorized removal from the place of storage.
 - b. Sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee.
 7. Procedures for picking up, receiving, and opening packages.
 - a. (1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in subdivision b shall:
 - (a) If the package is to be delivered to the licensee's facility by the carrier, make arrangements to receive the package when it is offered for delivery by the carrier; or
 - (b) If the package is to be picked up by the licensee at the carrier's terminal, make

arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

- (2) Each licensee who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its arrival.
- b. (1) Each licensee, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents, except:
- (a) Packages containing no more than the exempt quantity specified in the table in this subdivision.
 - (b) Packages containing no more than ten millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125.
 - (c) Packages containing only radioactive material as gases or in special form.
 - (d) Packages containing only radioactive material in other than liquid form (including Mo-99/Tc-99m generators) and not exceeding the Type A quantity limit specified in the table in this subdivision.
 - (e) Packages containing only radionuclides with half-lives of less than thirty days and a total quantity of no more than one hundred millicuries.

The monitoring shall be performed as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or eighteen hours if received after normal working hours.

- (2) If removable radioactive contamination in excess of one-hundredth microcurie (twenty-two thousand two hundred disintegrations per minute) per one hundred square centimeters of package surface is found on the external surfaces of the package, the licensee shall immediately notify by telephone and telegraph, the final delivering carrier and the department.

Table of Exempt and Type A Quantities

Transport group *	Exempt Quantity Limit (in millicuries)	Type A Quantity Limit (in curies)
I	0.01	0.001
II	0.1	0.050
III	1	3
IV	1	20
V	1	20
VI	1	1,000
VII	25,000	1,000
Special form *	1	20

* The definitions of "transport group" and "special form" are specified in section 33-10-01-04.

- c. (1) Each licensee, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified in subdivision b, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or eighteen hours if received after normal working hours.
- (2) If radiation levels are found on the external surface of the package in excess of two hundred millirem per hour, or at three feet [91.44 centimeters], from the external surface of the package in excess of ten millirem per hours, the licensee shall immediately notify, by telephone and telegraph, the final delivering carrier and the department.
- d. Each licensee shall establish and maintain procedures for safely opening packages in which radioactive material is received, and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 23-01-03

33-10-04-04. Waste disposal.

1. General requirement. No licensee shall dispose of any radioactive material except:
 - a. By transfer to an authorized recipient as provided in chapter 33-10-03; or
 - b. As authorized pursuant to subsection 6 of section 33-10-04-02 or subsection 2, 3, or 4 of this section.
2. Method of obtaining approval of proposed disposal procedures. Any person may apply to the department for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this chapter. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface water in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

The department will not approve any application for a license to receive radioactive material from other persons for disposal on land not owned by a state or the federal government.

3. Disposal by release into sanitary ~~sewerage~~ sewage systems. No licensee shall discharge radioactive material into a sanitary ~~sewerage~~ sewage system unless all of the following are met:
 - a. It is readily soluble or dispersible in water.
 - b. The quantity of any radioactive material released into the system by the licensee in any one day does not exceed the larger of paragraph 1 or 2:
 - (1) The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration not greater than the limits specified in Appendix A, Table I, Column 2, of this chapter.
 - (2) Ten times the quantity of such material specified in Appendix B of this chapter.

- c. The quantity of any radioactive material released in any one month, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix A, Table I, Column 2, of this chapter.
 - d. The gross quantity of licensed and other radioactive material excluding hydrogen-3 and carbon-14, released into the sanitary ~~sewerage~~ sewage system by the licensee does not exceed one curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary ~~sewerage~~ sewage system may not exceed five curies per year of hydrogen-3 and one curie per year for carbon-14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this subsection.
4. No licensee shall discharge radioactive material into an individual sewage disposal system used for the treatment of wastewater serving only a single dwelling, office building, industrial plant, or institution except as specifically approved by the department pursuant to subsection 6 of section 33-15-01-01 and subsection 2 of section 33-10-04-04.
5. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this subsection.
6. Disposal by burial in soil. No licensee shall dispose of radioactive material by burial in soil except as specifically approved by the department pursuant to subsection 2 of this section.
7. Disposal by incineration. No licensee shall incinerate radioactive material for the purpose of disposal or preparation for disposal except as specifically approved by the department pursuant to subsection 6 of section 33-10-04-02 and subsection 2 of this section.
- 5- 8. Disposal of specific wastes. Any licensee may dispose of the following licensed material without regard to its radioactivity:
- a. Five-hundredths ~~microcuries~~ microcurie or less of hydrogen-3 or carbon-14, per gram of medium, used for liquid scintillation ~~accounting~~ counting.
 - b. Five-hundredths microcurie or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal; provided, however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed.

- c. Nothing in this section, however, relieves the licensee of maintaining records showing the receipt, transfer, and disposal of such radioactive material.
- d. Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

9. Classification of radioactive waste for near-surface disposal.

a. Considerations. Determination of the classification of waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b. Classes of waste.

- (1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in subdivision a of subsection 10 of this section. If Class A waste also meets the stability requirements set forth in subdivision b of subsection 10 of this section, it is not necessary to segregate the waste for disposal.
- (2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in subsection 10 of this section.
- (3) Class C waste is waste that not only must meet more rigorous requirements on waste to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability

requirements set forth in subsection 10 of this section.

c. Classification determined by long-lived radionuclides. If the waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

- (1) If the concentration does not exceed one-tenth the value in Table 1, the waste is Class A.
- (2) If the concentration exceeds one-tenth the value in Table 1, the waste is Class C.
- (3) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.
- (4) For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in subdivision g of this subsection.

Table 1

<u>Radionuclide</u>	<u>Concentration curies/cubic meter</u>
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic radionuclides with half-life greater than five years	100 ¹⁴
Pu-241	3,500 ¹⁴
Cm-242	20,000 ¹⁴
Ra-226	100 ¹⁴

¹⁴ Units are nanocuries per gram

d. Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. If a nuclide is not listed in Table 2, it does not need to be considered in determining the waste class.

- (1) If the concentration does not exceed the value in Column 1, the waste is Class A.

- (2) If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class B.
- (3) If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.
- (4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.
- (5) For wastes containing mixtures of the radionuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in subdivision g of this subsection.

Table 2

Radionuclides	Concentration, curies/cubic meter		
	Column 1	Column 2	Column 3
Total of all radionuclides with less than five-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7,000
Sr-90	0.04	150	7,000
Cs-137	1	44	4,600

* There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table 2 determine the waste to be Class C independent of these radionuclides.

e. Classification determined by both long-lived and short-lived radionuclides. If the waste contains a mixture of radionuclides, some of which are listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:

- (1) If the concentration of a radionuclide listed in Table 1 is less than one-tenth the value listed in

Table 1, the class shall be that determined by the concentration of radionuclides listed in Table 2.

(2) If the concentration of a radionuclide listed in Table 1 exceeds one-tenth the value listed in Table 1, the waste shall be Class C, provided the concentration of radionuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.

f. Classification of wastes with radionuclides other than those listed in Tables 1 and 2. If the waste does not contain any radionuclides listed in either Table 1 or 2, it is Class A.

g. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column.

Example: A waste contains Sr-90 in a concentration of 50 Ci/m³ and Cs-137 in a concentration of 22/Ci/m³. Since the concentrations both exceed the values in Column 1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction, $50/150 = 0.33$; for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

h. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocuries per gram.

10. Radioactive waste characteristics.

a. The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the

conditions of the site license are more restrictive than the provisions of these rules, the site license conditions shall govern.

- (2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.
 - (3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.
 - (4) Solid wastes containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume.
 - (5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.
 - (6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with paragraph 8 of this subdivision.
 - (7) Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.
 - (8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed one and one-half atmospheres at twenty degrees Celsius. Total activity shall not exceed one hundred curies per container.
 - (9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.
- b. The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.
- (1) Waste shall have structural stability. A structurally stable waste form will generally

maintain its physical dimensions and its form, under the equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(2) Notwithstanding the provisions in paragraphs 3 and 4 of subdivision a of this subsection, liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or five-tenths percent of the volume of the waste for waste processed to a stable form.

(3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

11. Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with subsection 7 of this section.

12. Reserved.

13. Transfer for disposal and manifests.

a. Each shipment of waste to a licensed land disposal facility shall be accompanied by a shipment manifest that contains the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number of the person transporting the waste to the land disposal facility. The manifest shall also indicate as completely as practicable: a physical description of the waste; the waste volume; radionuclide identity and quantity; the total radioactivity; and the principal chemical form. The solidification agent shall be specified. Wastes containing more than one-tenth percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in subsection 7 of this section shall be clearly identified as such in the manifest except when transferring to a licensed waste processor who treats or repackages waste. The total quantity of the radionuclides H-3, C-14, Tc-99, and I-129 shall be shown.

- b. The manifest required in subdivision a of this subsection may be shipping papers used to meet United States department of transportation or United States environmental protection agency regulations or requirements of the receiver, provided all the required information is included.
- c. Each manifest shall include a certification by the waste generator that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the United States department of transportation and the department. An authorized representative of the waste generator shall sign and date the manifest.
- d. Any licensee who transfers waste to a land disposal facility or a licensed waste collector shall comply with the following requirements. Any licensee who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of paragraphs 4 through 8 of this subdivision. A licensee shall:
- (1) Prepare all wastes so that the waste is classified according to subsection 9 of this section and meets the waste characteristics requirements in subsection 10 of this section.
 - (2) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with subsection 9 of this section.
 - (3) Conduct a quality control program to assure compliance with subsections 9 and 10 of this section; the program must include management evaluation of audits.
 - (4) Prepare shipping manifests to meet the requirements of subdivisions a and b of this subsection.
 - (5) Forward a copy of the manifest to the intended recipient, at the time of shipment; or, deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest from the collector.
 - (6) Include one copy of the manifest with the shipment.
 - (7) Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these rules.

(8) Forward a copy of the manifest to the department.

(9) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this subsection conduct an investigation in accordance with subdivision h of this subsection.

e. Any waste collector licensee who handles only prepackaged waste shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest.

(2) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in subdivision b of this subsection. The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification.

(3) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment.

(4) Include the new manifest with the shipment to the disposal site.

(5) Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by this article, and retain information from generator manifests until disposition is authorized by the department.

(6) For any shipments or any part of a shipment for which acknowledgment of receipt is not received within the times set forth in this subdivision conduct an investigation in accordance with subdivision h of this subsection.

f. Any licensed waste processor who treats or repackages wastes shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest.

- (2) Prepare a new manifest that meets the requirements of subdivisions a, b, and c of this subsection. Preparation of the new manifest reflects that the processor is responsible for the waste.
- (3) Prepare all wastes so that the waste is classified according to subsection 9 of this section and meets the waste characteristics requirement in subsection 10 of this section.
- (4) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with subsections 9 and 11 of this section of this article.
- (5) A quality control program shall be conducted to assure compliance with subsections 9 and 10 of this section.
- (6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest by the collector.
- (7) Include the new manifest with the shipment.
- (8) Retain copies of original manifests and new manifests with documentation of acknowledgment of receipt as the record of transfer of licensed material required by this article.
- (9) For any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section, conduct an investigation in accordance with subdivision h of this subsection.

g. The land disposal facility operator shall:

- (1) Acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest shall indicate any discrepancies between materials listed on the manifest and materials received.
- (2) Maintain copies of all completed manifests until the department authorizes their disposition.

h. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

(1) Be investigated by the shipper if the shipper has not received notification of receipt within twenty days after transfer.

(2) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within two weeks of completion of the investigation.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 23-01-03

33-10-04-05. Records, reports, and notification.

1. Records of surveys, radiation monitoring, and disposal.

- a. Each licensee or registrant shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under subsection 2 of section 33-10-04-03. Such records shall be kept on Department Form RAD 683, in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by Department Form RAD 683. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.
- b. Each licensee or registrant shall maintain records in the same units used in this chapter, showing the results of surveys required by subsection 1 of section 33-10-04-03, monitoring required by subdivisions b and c of subsection 7 of section 33-10-04-03, and disposals made under subsections 2, 3, and 4 of section 33-10-04-04.
- c. Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of subdivision a and records of bioassays, including results of whole body counting examinations, made pursuant to subsection 7 of section 33-10-04-02 shall be preserved until the department authorizes disposition.
- d. Records of the results of surveys and monitoring which must be maintained pursuant to subdivision b shall be preserved for two years after completion of the survey

except that the following records shall be maintained until the department authorizes their disposition:

- (1) Records of the results of surveys to determine compliance with subdivision a of subsection 3 of section 33-10-04-02.
 - (2) In the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose.
 - (3) Records of the results of surveys used to evaluate the release of radioactive effluents to the environment.
- e. Records of disposal of licensed radioactive material made pursuant to subsection 2, 3, or 4 of section 33-10-04-04 shall be maintained until the department authorizes their disposition.
 - f. Records which must be maintained pursuant to this chapter may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by department regulations this chapter.
 - g. If there is a conflict between this chapter, license condition, or other written department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in this chapter for such records shall apply unless the department, pursuant to subsection 1 of section 33-10-01-05, has granted a specific exemption from the record retention requirements specified in this chapter.
 - h. The discontinuance of or curtailment of activities, does not relieve the licensee or registrant of responsibility for retaining all records required by this subsection. A licensee or registrant may, however, request the department to accept such records. The acceptance of the records by the department relieves the licensee or registrant of subsequent responsibility only in respect to their preservation as required by this subsection.
2. Reports of theft or loss of sources of radiation. Each licensee or registrant shall report by telephone and telegraph to the department the theft or loss of any source of radiation immediately after such occurrence becomes known.
 3. Notification of incidents.

- a. Immediate notification. Each licensee or registrant shall immediately notify the department by telephone and telegraph of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause any of the following:
- (1) A dose to the whole body of any individual of twenty-five rems or more of radiation; a dose to the skin of the whole body of any individual of one hundred fifty rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of three hundred seventy-five rems or more of radiation.
 - (2) The release of radioactive material in concentrations which, if averaged over a period of twenty-four hours, would exceed five thousand times the limits specified for such materials in Appendix A, Table II.
 - (3) A loss of one working week or more of the operation of any facilities affected.
 - (4) Damage to property in excess of two hundred thousand dollars.
- b. Twenty-four-hour notification. Each licensee or registrant shall within twenty-four hours notify the department by telephone and telegraph of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause any of the following:
- (1) A dose to the whole body of any individual of five rems or more of radiation; a dose to the skin of the whole body of any individual of thirty rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of seventy-five rems or more of radiation.
 - (2) The release of radioactive material in concentrations which, if averaged over a period of twenty-four hours, would exceed five hundred times the limits specified for such materials in Appendix A, Table II.
 - (3) A loss of one day or more of the operation of any facilities affected.
 - (4) Damage to property in excess of two thousand dollars.
- c. Any report filed with the department pursuant to this subsection shall be prepared in such a manner that names of individuals who have received excessive doses will be stated in a separate part of the report.

4. Reports of overexposures and excessive levels and concentrations.
 - a. In addition to any notification required by subsection 3, each licensee or registrant shall make a report, in writing, within thirty days to the department of (1) each exposure of an individual to radiation or concentrations of radioactive material in excess of any applicable limit as set forth in this ~~regulation~~ article or as otherwise approved by the department; (2) any incident for which notification is required by subsection 3; and (3) levels of radiation or concentrations of radioactive material (not involving excessive exposure of any individual) in an unrestricted area in excess of ten times any applicable limit as set forth in this chapter or as otherwise approved by the department. Each report required under this subdivision shall describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's dose as required by levels of radiation and concentrations of radioactive material of this subsection involved; the cause of exposure, levels or concentrations; and corrective steps taken or planned to assure against a recurrence.
 - b. Any report filed with the department pursuant to this subsection shall include for each individual exposed the name, social security number, and date of birth, and an estimate of the individual's dose. The report shall be prepared so that this information is stated in a separate part of the report.
5. Vacating premises and equipment. ~~Each specific licensee shall, no less than thirty days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities, notify the department, in writing, of intent to vacate. When deemed necessary by the department, the licensee shall decontaminate the premises in such a manner as the department may specify.~~
 - a. Premises. Each licensee before vacating any premise, or transferring the premise shall permanently decontaminate such premise below or equal to the standards specified in Appendix C of this chapter. A survey shall be made after such decontamination and the department and the landlord or subsequent tenant or transferee shall be provided with a copy of such survey no less than thirty days before vacating or relinquishing possession or control of premise. No such premise may be vacated, sold, or transferred until the decontamination survey has been verified and accepted by the department.

b. Equipment. No machinery, instruments, laboratory equipment, or any other property used in contact with, or close proximity to radioactive material at a licensed premise may be assigned, sold, leased, or transferred to an unlicensed person unless such property has been permanently decontaminated below or equal to the standards specified in Appendix C of this chapter. A survey shall be made after such decontamination and the department and subsequent transferee or owner shall be provided with a copy of such survey. No such equipment may be assigned, sold, leased, or transferred until such documentation survey has been verified and accepted by the department.

6. Notifications and reports to individuals.

- a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in subsection 3 of section 33-10-10-01.
- b. When a licensee or registrant is required pursuant to subsection 4 to report to the department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the department, and shall comply with the provisions of subsection 3 of section 33-10-10-01.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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 regulations applicable requirements of this article.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-05-03. Definitions. As used in this chapter:

1. "Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.
 - a. "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the conditions specified in subsection 5 of section 33-10-04-02.

- (1) "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, 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 x 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.
- (2) "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.
 - b. "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 of section 33-10-04-02.
2. "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.
3. "Permanent radiographic installation" means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.
4. "Personal supervision" means supervision such that the supervisor is physically present at the **radiography** site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant and in such proximity that **contact can be maintained and immediate assistance can be given** as required.
5. "Radiographer" means any individual who performs, or provides personal supervision of, industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of **these regulations** this article and all license (or certificate of registration) conditions.
6. "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

7. "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.
8. "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.
9. "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.
10. "Storage container" means a device in which sealed sources are transported or stored.
11. "Temporary jobsite" means any location where industrial radiography is performed other than the locations listed in a specific license or certificate of registration.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-05-04. Equipment control.

1. Limits on levels of radiation for radiographic exposure devices and storage containers. 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 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 per hour at any exterior surface, and ten milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.
2. Locking of sources of radiation.
 - a. Each source of radiation shall be provided with a lock or outer-locked 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's assistant, or as may be otherwise authorized pursuant to subsection 1 of section 33-10-05-06. Each storage container and source changer likewise shall be provided with a lock and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

- b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured to a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.
3. Storage precautions. Locked radiographic exposure devices, source changers, source containers, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.
4. Radiation survey instruments. 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. Each radiation survey instrument shall be calibrated at energies appropriate for use, at intervals not to exceed three months and after each instrument servicing and a, such that accuracy within plus or minus twenty percent can be demonstrated at two or more widely separated points, other than zero, on each scale. A record shall be maintained of the latest date of calibration. Instrumentation required by this subsection shall have a range such that two milliroentgens per hour through one roentgen per hour can be measured.
5. 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 of removable contamination

on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to paragraph 5 of subdivision e of subsection 3 of section 33-10-03-05. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department for six months after the next required leak test is performed or until the sealed source is transferred or disposed.

- d. Any test conducted pursuant to subdivisions b and c which reveals the presence of five-thousandths microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with ~~regulations of the department~~ this article. Within five days after obtaining results of the test, the licensee shall file a report with the department describing the equipment involved, the test results, and the corrective action taken.
 - e. A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one inch [2.54 centimeters] square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found".
6. Quarterly inventory. Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received or possessed by the licensee. The records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, the location of sealed sources, and the date of the inventory.
 7. Utilization logs. Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the department showing for each source of radiation the following information:
 - a. A description (or make and model number) of each source of radiation or storage container in which the sealed source is located.
 - b. The identity of the radiographer to whom assigned.
 - c. Locations where used and dates of use.

8. Inspection and maintenance of radiographic exposure devices, storage containers, and source changers.
 - a. The licensee shall check for obvious defects in radiation machines, radiographic devices, storage containers, and source changers prior to use each day the equipment is used.
 - b. The licensee shall conduct a program for inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers at intervals not to exceed three months or prior to the first use thereafter 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 until it authorizes their disposal.
 - 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 until repairs have been made.
9. Permanent radiographic installations. Permanent radiographic installations having high radiation area entrance controls of the types described in subsection 3 of section 33-10-05-05 shall also meet the following requirements:
 - a. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.
 - b. A control device or alarm system shall be tested for proper operation at the beginning of each period of use. Records of such tests shall be maintained for inspection by the department until it authorizes their disposal.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-05-05. Personal radiation safety requirements for radiographers and radiographers' assistants.

1. Training and testing.

- a. The licensee or registrant shall not permit any individual to act as a radiographer until such individual:
- (1) Has been instructed in the subjects outlined in Appendix A of this ~~part~~ chapter;
 - (2) Has received copies of and instruction in department ~~regulations~~ requirements contained in this ~~part~~ chapter and in the applicable sections of chapters 33-10-04 and 33-10-10, department license under which the radiographer will perform radiography, and the licensee's operating and emergency procedures;
 - (3) Has demonstrated competence to use the licensee's radiographic exposure devices, sealed sources, related handling tools, and survey instruments; and
 - (4) Has demonstrated understanding of the instructions in this paragraph by successful completion of a written test and a field examination on the subjects covered.
- b. The licensee or registrant shall not permit any individual to act as a radiographer's assistant until such individual:
- (1) Has received copies of and instruction in the licensee's operating and emergency procedures;
 - (2) Has demonstrated competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, and radiation survey instruments that the assistant will use; and
 - (3) Has demonstrated understanding of the instructions in this paragraph by successfully completing a written or oral test and a field examination on the subjects covered.
- c. Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained 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 and radiographer's assistant. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least annually. 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 and, source changers, storage containers, and radiation machines.
3. Personnel monitoring control.
 - a. No licensee or registrant shall permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual shall wear a direct-reading pocket dosimeter and either film badge or a thermoluminescent dosimeter badge. Pocket dosimeters shall have a range from zero to at least two hundred milliroentgens and shall be recharged daily or at the start of each shift. Each badge and thermoluminescent dosimeter shall be assigned to and worn by only one individual.

- b. Pocket dosimeters shall be read and exposures recorded daily.
 - c. Pocket dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus thirty percent of the true radiation exposed exposure.
 - d. An individual's film badge or thermoluminescent dosimeter shall be immediately processed if a pocket dosimeter is discharged beyond its range.
 - e. Reports received from the badge or thermoluminescent dosimeter processor and records of pocket dosimeter readings shall be maintained for inspection by the department.
4. Supervision of radiographers' assistants. Whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by subsection 3 of section 33-10-05-06 to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision shall include:
- a. The radiographer's personal presence at the site where the sealed sources are being used.
 - b. The ability of the radiographer to give immediate assistance if required.
 - c. The radiographer's watching the assistant's performance of the operations referred to in this section.

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

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's assistant 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 of section 33-10-04-03, or (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 of section 33-10-04-03, 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 of section 33-10-04-03.
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 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 guide tube.
 - c. A physical radiation survey shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device or storage container, as specified in subsection 2 of section 33-10-05-04.
 - d. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off".
 - e. A record of the survey required in subdivision b Records shall be kept of the surveys required by subdivisions c and d. Such records shall be maintained for inspection by the department when the survey is the last survey prior to locking the radiographic exposure device and ending direct surveillance of the operation for two years.
4. Records required at temporary jobsites. Each licensee or registrant conducting industrial radiography at a temporary site 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 ~~regulations~~ 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. Special requirements and exemptions for enclosed radiography.
- a. Systems for enclosed radiography designed to allow admittance of individuals shall:
 - (1) Comply with all applicable requirements of this part and subsection 5 of section 33-10-04-02. 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. Cabinet X-ray systems designed to exclude individuals are exempt from the requirements of this chapter except that:
 - (1) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and reports of the results must be maintained for inspection by the department.
 - (2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this paragraph shall be maintained for inspection by the agency department until disposition is authorized by the department.
 - (3) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, must be conducted and recorded in accordance with subsection 9 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 of section 33-10-05-04. 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.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
2. "Added filtration" means any filtration which is in addition to the inherent filtration.
3. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is ninety-nine percent minimum aluminum, twelve-hundredths percent copper.)
4. "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

5. "Attenuation block" means a block or stack, having dimensions twenty centimeters by twenty centimeters by three and eight-tenths centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.
6. "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location or locations a required quantity of radiation (See also "phototimer").
7. "Barrier" (see "protective barrier").
8. "Beam axis" means a line from the source through the centers of the X-ray fields.
9. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the X-ray field.
10. "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.
11. "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
12. "Certified components" means components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 [Pub. L. 90-602].
13. "Certified system" means any X-ray system which has one or more certified component or components.
14. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.
15. "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

where:

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

16. "Contact therapy system" means an X-ray system used for therapy with the X-ray tube port placed in contact with or within five centimeters of the surface being treated.
17. "Control panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.
18. "Cooling curve" means the graphical relationship between heat units stored and cooling time.
19. "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
20. "Detector" means radiation detector.
21. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
22. "Diagnostic X-ray system" means an X-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
23. "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "scattered radiation").
24. "Entrance exposure rate" means the ~~roentgens~~ exposure per unit time at the point where the center of the useful beam enters the patient.
25. "Equipment" means X-ray equipment.
26. "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the

electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. (The special unit of exposure is the roentgen.)

When the word exposure is used in this chapter to mean one or more irradiations of a person for a healing arts purpose, or in a more general sense, it will not be underlined.

- ~~27-~~ 26. "Field emission equipment" means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- ~~28-~~ 27. "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
- ~~29-~~ 28. "Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptor or receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
29. "Focal spot" means the area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.
- ~~30-~~ "Full beam detector" means a radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.
- ~~31-~~ 30. "General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
- ~~32-~~ 31. "Gonad shield" means a protective barrier for the testes or ovaries.
- ~~33-~~ 32. "Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- ~~34-~~ 33. "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.

- ~~35-~~ 34. "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x seconds.
- ~~36-~~ 35. "HVL" means half-value layer.
- ~~37-~~ 36. "Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.
- ~~38-~~ 37. "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.
- ~~39-~~ 38. "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.
- ~~40-~~ 39. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
- ~~41-~~ 40. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
- ~~42-~~ 41. "Irradiation" means the exposure of matter to ionizing radiation.
- ~~43-~~ 42. "Kilovolts peak" means peak tube potential.
- ~~44-~~ 43. "kV" means kilovolts.
- ~~45-~~ 44. "kVp" means peak tube potential.
- ~~46-~~ 45. "kWs" means kilowatt second. It is equivalent to 10^3 kV·mA·s,

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

- ~~47-~~ 46. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- ~~48-~~ 47. "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:
- a. The useful beam.

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

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

- a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, i.e., ten milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.
- b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- c. For all other equipment diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

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

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

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

where:

V_n = No-load line potential and

V_l = Load line potential

52- 51. "mA" means milliamperere.

53- 52. "mAs" means milliamperere second.

- ~~54-~~ 53. "Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.
- ~~55-~~ 54. "Mobile X-ray equipment" (See "X-ray equipment").
- ~~56-~~ 55. "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.
- ~~57-~~ 56. "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated (See "automatic exposure control").
- ~~58-~~ 57. "PID" means position indicating device.
58. "Portable X-ray equipment" (see "X-ray equipment").
59. "Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
60. "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.
- ~~60-~~ 61. "Primary protective barrier" means protective barrier.
- ~~61-~~ 62. "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.
- ~~62-~~ 63. "Protective barrier" means a barrier of radiation absorbing material or materials used to reduce radiation exposure. The types of protective barriers are as follows:
- a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
 - b. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
- ~~63-~~ 64. "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.
- ~~64-~~ 65. "Qualified expert" means an individual who has demonstrated to the satisfaction of the department that such individual possesses the knowledge and training to measure ionizing

radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

- ~~65-~~ 66. "Radiation detector" means a device which in the presence of radiation provides ~~by either direct or indirect means,~~ a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
- ~~66-~~ 67. "Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
- ~~67-~~ 68. "Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.
- ~~68-~~ 69. "Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.
70. "Radiological physicist" means an individual who:
- a. Is certified by the American board of radiology in therapeutic radiological physics, radiological physics, or X-ray and gamma-ray physics;
 - b. Has a bachelor's degree in one of the physical sciences or engineering and three year's full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American board of radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - c. Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.
- ~~69-~~ 71. "Rating" means the operating limits as specified by the component manufacturer.
- ~~70-~~ 72. "Recording" means producing a permanent form of an image resulting from X-ray photons, ~~e.g., film, video tape.~~
- ~~71-~~ "Registrant" means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans

or animals to the useful beam of the system and is required by chapters 33-10-01 and 33-10-02 to register with this department.

- ~~72-~~ 73. "Response time" means the time required for an instrument system to reach ninety percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady-state midscale reading.
- ~~73-~~ 74. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "direct scattered radiation").
75. "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.
- ~~74-~~ 76. "Secondary protective barrier" means protective barrier.
- ~~75-~~ 77. "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
- ~~76-~~ 78. "SID" means source-image receptor distance.
- ~~77-~~ 79. "Source" means the focal spot of the X-ray tube.
- ~~78-~~ 80. "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.
- ~~79-~~ 81. "Spot check" means an abbreviated calibration a procedure which is performed to assure that a previous calibration continues to be valid.
- ~~80-~~ 82. "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- ~~81-~~ 83. "Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
84. "SSD" means the distance between the source and the skin of the patient.
- ~~82-~~ 85. "Stationary X-ray equipment" means X-ray equipment.

- 83- 86. "Stray radiation" means the sum of leakage and scattered radiation.
- 84- 87. "Technique factors" means the conditions of operation. They are specified as follows:
- a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.
 - b. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses.
 - c. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- 85- **"Transmission detector" means a radiation detector through which the useful beam or part of the useful beam passes-**
- 86- **"Treatment volume" means the region, in the patient, to which a specified dose is intended to be delivered-**
88. "Termination of radiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
89. "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- 87- 90. "Tube" means an X-ray tube, unless otherwise specified.
- 88- 91. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
- 89- 92. "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
- 90- 93. "Useful beam" means the radiation which passes emanating from the tube housing port or the radiation head and passing through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated controls are in a mode to cause the system to produce radiation.

- ~~91-~~ 94. "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given source-image receptor distance.
- ~~92-~~ 95. "Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.
- ~~93-~~ 96. "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
- ~~94-~~ 97. "X-ray control" means a device which controls input power to the X-ray high-voltage generator or the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.
- ~~95-~~ 98. "X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:
- a. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
 - b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.
 - c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.
- ~~96-~~ 99. "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- ~~97-~~ 100. "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube, high-voltage switches, electrical protective devices, and other appropriate elements.
- ~~98-~~ 101. "X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, and X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
- ~~99-~~ 102. "X-ray subsystem" means any combination of two or more components of an X-ray system.

~~100-~~ 103. "X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-06-03. General requirements.

1. Administrative controls.

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

(1) An X-ray system which does not meet the provisions of this ~~article~~ chapter shall not be operated for diagnostic or therapeutic purposes, if so directed by the department.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction should consist of subjects outlined in Appendix F of this chapter.

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

(a) Patient's anatomical size versus technique factors to be utilized.

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

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

(d) Source to image receptor distance to be used.

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

(4) Written safety procedures and rules shall be provided to each individual operating X-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular X-

ray system. The operator shall be able to demonstrate familiarity with ~~these rules~~ this article.

- (5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - (a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by five-tenths millimeter lead equivalent.
 - (b) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than twenty-five hundredths millimeter lead equivalent.
 - (c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of twenty-five hundredths millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.
- (6) Gonad shielding of not less than twenty-five hundredths millimeter lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- (7) Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purpose:
 - (a) Exposure of an individual for training, demonstration or other non-healing-arts purposes; and
 - (b) Exposure of an individual for the purpose of healing arts screening except as authorized by paragraph ± 11.
- (8) When a patient or film must be provided with auxiliary support during a radiation exposure:

- (a) Mechanical holding devices shall be used when the technique permits. The safety rules, required by this section shall list individual projections where holding devices cannot be utilized.
 - (b) Written safety procedures, as required by paragraph 4, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.
 - (c) The human holder shall be protected as required by paragraph 5.
 - (d) No individual shall be used routinely to hold film or patients.
- ~~(e) Such holding shall be permitted only in very unusual and rare situations.~~
- ~~(f)~~ (e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five-tenths millimeter lead equivalent material.
 - ~~(g)~~ (f) A record shall be made of the examination and shall include the name of the human holder, date of the examination, number of exposures, and technique factors utilized for the exposure.
- (9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:
- (a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
 - (b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 - (c) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patients to a stationary radiographic X-ray installation.

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

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of subsections 1 and 2 of section 33-10-04-02. In addition:

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

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

[2] The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by subsection 1 of section 33-10-04-05. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

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

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

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

(1) Maximum rating of technique factors.

(2) Model and serial numbers of all certifiable components.

- (3) Aluminum equivalent filtration of the useful beam, including any routine variation.
 - (4) Tube rating charts and cooling curves.
 - (5) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system after the effective date of section 33-10-06-03 with the names of persons who performed such services.
 - (6) A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
 - (a) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
 - (b) The type and thickness of materials, or lead equivalency, or each protective barrier.
 - (7) A copy of all correspondence with this department regarding that X-ray system.
- c. X-ray log. Each facility shall maintain an X-ray log containing the examinations and the dates those examinations were performed. The log shall indicate when the techniques or procedures vary from those specified in the technique chart required in paragraph 3 of subdivision a of subsection 1. The log shall contain the information required by paragraphs 7 and 9 of subdivision a of subsection 1 patient's name, the type of examinations, and the dates those examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

2. Plan review.

- a. Prior to construction, the floor plans and equipment arrangement or all new installations, or modifications of existing installations, utilizing X-rays for diagnostic or therapeutic purposes shall be submitted to the agency department for review and approval. The required information is denoted in Appendices A and B of this chapter.

- b. The department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.
- c. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in subsections 1, 4, and 5 of section 33-10-04-02 of these regulations.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
2. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
3. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed one hundred milliroentgens in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.
4. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.
5. Beam quality.
 - a. Half-value layer.

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

TABLE I

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts peak)	Half-value Layer (Millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

- (2) The above half-value layer criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

<u>Filtration Required vs. Operating Voltage</u>	
Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

(3) In addition to the requirements of paragraph 1, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than one and one-half millimeters aluminum equivalent filtration permanently installed in the useful beam.

←3→ (4) Beryllium window tubes shall have a minimum of five-tenths millimeter aluminum equivalent filtration permanently installed in the useful beam.

←4→ (5) For capacitor energy storage equipment, compliance with the requirements of this subsection shall be determined with the maximum quantity of charge per exposure.

←5→ (6) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

b. Filtration controls. For X-ray systems which have variable kilovolts peak and variable filtration for the useful beam, a device shall link the kilovolts peak selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by paragraphs 1 or 2 of subdivision a is in the useful beam for the given kilovolts peak which has been selected.

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

7. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.
8. Technique indicators.
 - a. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.
 - b. The requirements of subdivision a may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operators position except in the case of spot films made by the fluoroscopist.
9. Focal spot indication. [Reserved]
10. Structural shielding requirements (See Appendix C).

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. Limitation of useful beam.
 - a. Primary barrier.
 - (1) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-image receptor distance.
 - (2) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.
 - b. X-ray field.
 - (1) The X-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

- (a) Means shall be provided for stepless adjustment of the field size;
 - (b) The minimum field size at the greatest source-image receptor distance shall be equal to or less than five centimeters by five centimeters;
 - (c) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the X-ray beam is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and
 - (d) Compliance with this paragraph shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (2) For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the source-image receptor distance. The sum of the excess length and the excess width shall be no greater than four percent of the source-image receptor distance. In addition:
- (a) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable source-image receptor distance and/or a visible area of greater than three hundred square centimeters shall be provided with means for stepless adjustment of the X-ray field;
 - (b) The minimum field size at the greatest source-image receptor distance shall be equal to or less than five centimeters by five centimeters; All equipment with a fixed source-image receptor distance and a visible area of three hundred square centimeters or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to one hundred twenty-five square centimeters or less. Stepless adjustment shall, at the greatest source-image receptor distance, provide continuous field sizes from the maximum obtainable to a field size of five by five centimeters or less;

- (c) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and
 - (d) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.
- (3) Spot-film devices which are certified components shall meet the following additional requirements:
- (a) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the ~~plane~~ plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
 - (b) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest source-image receptor distance shall be equal to, or less than, five centimeters by five centimeters;
 - (c) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the source-image receptor distance; and
 - (d) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and

compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure or exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.
3. Exposure rate limits.
 - a. Entrance exposure rate allowable limits.
 - (1) The exposure measured at the point where the center of the useful beam enters the patient shall not exceed ten roentgens per minute, except during recording of fluoroscopic images or when provided with optional high level control.
 - (2) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.
 - (a) Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.
 - (b) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
 - (3) In addition to the other requirements of this section, certified equipment which does not incorporate an automatic exposure control shall not be operable at any combination of tube potential and current which will result in any exposure rate in excess of five roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.
 - (4) Compliance with the requirements of ~~this~~ subsection 3 of this section shall be determined as follows:

- (a) Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - (b) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.
 - (c) If the source is above the table, the exposure rate shall be measured at thirty centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 - (d) In a C-arm type of fluoroscope, the exposure rate shall be measured thirty centimeters from the input surface of the fluoroscopic imaging assembly.
- (5) Periodic measurement of entrance exposure rate shall be performed as follows:
- (a) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
 - (b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in paragraph 5 of subdivision b of subsection 1 of section 33-10-06-03. Results of the measurements shall include the roentgen per minute, as well as the technique factors used to determine such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.
 - (c) Use of monitoring devices, e.g., commercially available film badges, thermoluminescent dosimeters, or low energy dosimeters, Personnel monitoring devices may be used to perform the measurements required by subparagraph a provided the measurements are made as described in subparagraph d.
 - (d) Conditions of periodic measurements of entrance exposure rate are as follows:
 - [1] The measurement shall be made under the conditions that satisfy the requirements of paragraph 4.

[2] The kilovolts peak shall be the kilovolts typical of clinical use of the X-ray system.

[3] The X-ray systems that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the X-ray system.

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

4. Barrier transmitted radiation rate limits.

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

b. Measuring compliance of barrier transmission.

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

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

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

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

- (5) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
5. Indication of potential and current. During fluoroscopy and cinefluorography, the kilovolt and the milliampere shall be continuously indicated.
6. Source-skin distance. The source to skin distance shall not be less than:
 - a. Thirty-eight centimeters on stationary fluoroscopes installed after the effective date of this regulation, September 1, 1968.
 - b. Thirty-five centimeters on stationary fluoroscopes which are in operation prior to the effective date of these regulations, October 1, 1982.
 - c. Thirty centimeters on all mobile fluoroscopes, and.
 - d. Twenty centimeters for image intensified fluoroscopes used for specific surgical application. The users operating manual written safety procedures must provide precautionary measures to be adhered to during the use of this device.
7. Fluoroscopic timer.
 - a. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
 - b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.
8. Mobile fluoroscopes. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.
9. Control of scattered radiation.
 - a. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not

less than twenty-five hundredths millimeter lead equivalent.

- b. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:
 - (1) Is at least one hundred twenty centimeters from the center of the useful beam; or
 - (2) The radiation has passed through not less than twenty-five hundredths millimeter lead equivalent material, e.g., drapes, bucky-slot cover-sliding or folding panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in paragraph 5 of subdivision a of subsection 1 of section 33-10-06-03.
 - c. Exceptions to subdivision b of this subsection may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.
10. Radiation therapy simulation system. Radiation therapy simulation systems shall be exempt from all the requirements of subsections 1, 4, and 7 of section 33-10-06-05 provided that:
- a. Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and
 - b. Such systems as do not meet the requirements of subsection 7 of section 33-10-06-05 are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.
11. Structural shielding requirements (See Appendix C).

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-06-06. Radiographic systems other than fluoroscopic, dental intraoral, or veterinarian systems.

1. Beam limitations. The useful beam shall be limited to the area of clinical interest.

a. General purpose stationary and mobile X-ray systems.

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

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

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

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

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

b. Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of subdivision a of this subsection, all stationary X-ray systems shall meet the following requirements:

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

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

(3) Indication of field size dimensions and source-image receptor distance's shall be specified in inches or centimeters, and shall be such that aperture

adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the source-image receptor distance when the beam axis is indicated to be perpendicular to the plane of the image receptor.

- c. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at the fixed source-image receptor distance shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within two percent of the source-image receptor distance, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
- d. Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent of the source-image receptor distance. This requirement can be met with a system which performs as prescribed in paragraph 3 of subdivision e of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the source-image receptor distance may vary, the source-image receptor distance indication specified in subparagraphs a and b of paragraph 3 of subdivision e of this subsection shall be the maximum source-image receptor distance for which beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.
- e. Special purpose X-ray systems.
 - (1) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the source-image receptor distance when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

- (2) Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the source-image receptor distance, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
- (3) Paragraphs 1 and 2 of this subdivision may be met with a system that meets the requirements for a general purpose X-ray system as specified in ~~this~~ subsection 1 of this section, or, when alignment means are also provided, may be met with either:
 - (a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and source-image receptor distance for which it is designed; or
 - (b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and source-image receptor distance for which each aperture is designed and shall indicate which aperture is in position for use.

2. Radiation exposure control devices.

- a. Timers. Means shall be provided to terminate the exposure at the preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
- b. X-ray control (exposure switch).
 - (1) A control which shall be the equivalent of a dead-man switch shall be incorporated into each X-ray system such that an exposure can be terminated at any time except for:
 - (a) Exposure of one-half second or less; or

- (b) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
- (2) Each X-ray control shall be located in such a way as to meet the following requirements:
 - (a) Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure (See Appendix B).
 - (b) Mobile and portable X-ray systems which are:
 - [1] Used for greater than one week in one location (one room or suite) shall meet the requirements of subparagraph a.
 - [2] Used for greater than one hour and less than one week at one location, (one room or suite) shall meet the requirement of item 1 of this subparagraph or be provided with a six and one-half foot [1.98-meter] high protective barrier which is placed at least six feet [1.83 meters] from the tube housing assembly and at least six feet [1.83 meters] from the patient.
 - [3] Used to make an exposure of only one patient at the use location shall meet the requirement of item 1 or 2 of this subparagraph or be provided with a method of X-ray control which will permit the operator to be at least twelve feet [3.66 meters] from the tube housing assembly during an exposure.
 - (c) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
- c. Automatic exposure controls. When an automatic exposure control is provided:
 - (1) Indication shall be made on the control panel when this mode of operation is selected;
 - (2) If the X-ray tube potential is equal to or greater than fifty kilovolts peak, the minimum exposure time for field emission equipment rated for pulsed

operation shall be equal to or less than a time interval equivalent to two pulses;

- (3) The minimum exposure time for all equipment other than that specified in paragraph 2 shall be equal to or less than one-sixtieth second or a time interval required to deliver five milliamperere seconds, whichever is greater;
 - (4) Either the product of the peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty kilowatt seconds per exposure or the product of X-ray tube current and exposure time shall be limited to not more than six hundred milliamperere seconds per exposure except when the X-ray tube potential is less than fifty kilovolts peak in which case the ~~produce~~ product of X-ray tube current and exposure time shall be limited to not more than two hundred milliamperere seconds per exposure; and
 - (5) A visible signal shall indicate when an exposure has been terminated at the limits required by paragraph 4, and manual resetting shall be required before further automatically timed exposures can be made.
- d. Reproducibility. With a timer setting of five-tenths seconds or less, the average exposure period (\bar{T}) shall be greater than or equal to five times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when four tests are performed.

$$\text{i.e., } \bar{T} \geq 5(T_{\max} - T_{\min}).$$

3. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to not less than thirty centimeters.
4. Exposure reproducibility. The exposure reproducibility shall meet the following requirements:

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

$$\text{i.e., } \bar{E} \geq 5(E_{\max} - E_{\min}).$$

5. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
6. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified components shall be required to comply with the following additional requirements which relate to that certified components.
 - a. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than five-hundredths for any specific combination of selected technique factors.
 - b. Linearity. When the equipment allows a choice of X-ray tube current settings and is operated on power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than ten-hundredths times their sum,

$$\text{i.e., } |\bar{X}_1 - \bar{X}_2| \leq 0.10 (\bar{X}_1 + \bar{X}_2),$$

where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

- c. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
- d. Beam limitation for stationary and mobile general purpose X-ray systems.
 - (1) There shall be provided a means of stepless adjustment of the size of the X-ray field. The minimum field size at ~~an~~ a source-image receptor

distance of one hundred centimeters shall be equal to or less than five centimeters by five centimeters.

- (2) When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than one hundred sixty lux or fifteen foot-candles at one hundred centimeters or at the maximum source-image receptor distance, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.
 - (3) The edge of the light field at one hundred centimeters or at the maximum source-image receptor distance, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three millimeters from the edge of the light field toward the center of the ~~light~~ field; and I_2 is the illumination three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.
- e. Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of subdivision a of subsection 1 and subdivision d ~~of this subsection~~ of subsection 6 of section 33-10-06-06.
- f. Field limitation and alignment on stationary general purpose X-ray systems. The requirements of this subdivision shall apply to assembly, an X-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c).
- (1) Means shall be provided for positive beam limitation which will, at the source-image receptor distance for which the device is designed, either cause automatic adjustment of the X-ray field in the plane of the image receptor to the image receptor size within five seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five seconds or is manual, will prevent production of X-rays until such adjustment is completed. For the source-image receptor distance at which the device is not intended to operate, the device shall prevent the production of X-rays.

- (2) The X-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the X-ray field differs from that of the image receptor by greater than three percent of the source-image receptor distance and that the sum of the length and width differences without regard to sign be no greater than four percent of the source-image receptor distance when the equipment indicated that the beam axis is perpendicular to the plane of the image receptor.
 - (3) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of one hundred centimeters shall be equal to or less than five centimeters by five centimeters. Return to positive beam limitation as specified in paragraphs 1 and 2 shall occur upon a change in image receptor.
 - (4) Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not either ten degrees of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.
 - (5) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overridden.
- g. Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
 - h. Transmission limit for image receptor supporting devices used for mammography. For X-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beams through the image receptor support provided with the system will be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed one-tenth milliroentgen for each activation of the tube. Exposure

shall be measured with the system operated at the minimum source-image receptor distance for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (milliamperere second) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:
 - a. Eighteen centimeters if operable above fifty kilovolts peak.
 - b. Ten centimeters if not operable above fifty kilovolts peak.
2. Field limitation.
 - a. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:
 - (1) If the minimum source-to-skin distance (SSD) is eighteen centimeters or more, the X-ray field, at the minimum source-to-skin distance, shall be containable in a circle having a diameter of no more than seven centimeters.
 - (2) If the minimum source-to-skin distance is less than eighteen centimeters, the X-ray field, at the minimum source-to-skin distance, shall be containable in a circle having a diameter of no more than six centimeters.
 - b. An open-ended ~~shield~~ shielded position indicating device shall be used. The shielding shall be equivalent to the requirements of subsection 4 of section 33-10-06-04.

3. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:
- a. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.
 - b. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
 - c. Accuracy. All timers shall be accurate to within \pm ten percent of the selected value.
 - d. Reproducibility. When four timer tests taken at identical timer settings are performed the average time period (\bar{T}) shall be greater than five times the maximum period (T_{\max}) less the minimum period (T_{\min}). \bar{T} shall be less than or equal to five seconds.

$$\bar{T} \text{ is greater than } 5 (T_{\max} - T_{\min})$$

4. X-ray control (exposure switch).
- a. A control which shall be the equivalent of a dead-man switch shall be incorporated into each X-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less.
 - b. Each X-ray control shall be located in such a way as to meet the following criteria:
 - (1) Stationary X-ray systems, shall have the control switch permanently mounted in a protected area, e.g., corridor outside the room, so that the operator is required to remain in that protected area during the entire exposure.
 - (2) Mobile and portable X-ray systems which are:
 - (a) Used for greater than one week in one location (one room or suite) shall meet the requirements of paragraph 1 of this subdivision.
 - (b) Used for more than one hour and less than one week at one location (one room or suite) shall meet the requirements of subparagraph a of this paragraph or be provided with a six and one-half foot [1.98-meter] high protective barrier which is placed at least six feet [1.83 meters] from

the tube housing assembly and at least six feet [1.83 meters] from the patient.

- (c) Used to make an exposure of only one patient at the use location shall meet the requirement requirements of items 1 and 2 of subparagraph b of paragraph 2 of subdivision b of subsection 2 of section 33-10-06-06 subparagraph a or b of this paragraph or be provided with a method of control which will permit the operator to be at least twelve feet [3.66 meters] from the tube head assembly during an exposure.

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

5. Exposure reproducibility. The exposure reproducibility shall meet the following requirements.

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

$$\text{i.e., } \bar{E} \geq 5(E_{\max} - E_{\min}).$$

6. Administrative controls.

- a. Patient and film holding devices shall be used when the techniques permit.
- b. Neither the tube housing nor the position indicating device shall be hand-held during an exposure.
- c. The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subdivision a of subsection 2 of this section.
- d. Dental fluoroscopy without image intensification shall not be used.

7. Additional requirements applicable to certified systems only. Only diagnostic X-ray systems incorporating one or more

certified components shall be required to comply with the following additional requirements which relate to that certified component.

- a. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than five-hundredths for any specific combination of selected technique factors.
- b. Linearity. When the equipment allows a choice of X-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rating, the average ratios of exposure to the indicated milliamperereconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than ten-hundredths times their sum,

$$\text{i.e., } |\bar{X}_1 - \bar{X}_2| \leq 0.10 (\bar{X}_1 + \bar{X}_2),$$

where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

- c. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
- d. Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
- e. Beam quality. All certified dental X-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than one and one-half millimeters aluminum equivalent. Systems operating above seventy kilovolts peak are subject to the filtration requirements of subdivision a of subsection 5 of section 33-10-06-04.

8. Structural shielding requirements (see Appendix C).

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. Equipment requirements.

- a. Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that X-ray system.
- (1) Contact therapy systems. Leakage radiation shall not exceed one hundred milliroentgens per hour at five centimeters from the surface of the tube housing assembly.
 - (2) 0-150 kilovolts peak systems. Systems which are manufactured or installed prior to ~~the effective date of this section~~ October 1, 1982, shall have a leakage radiation which does not exceed one roentgen in one hour at one meter from the source.
 - (3) 0-150 kilovolts peak systems. Systems which are manufactured on or after ~~the effective date of this section~~ October 1, 1982, shall have a leakage radiation which does not exceed one hundred milliroentgens in one hour at one meter from the source.
 - (4) 151 ~~to~~-999 kilovolts peak systems. The leakage radiation shall not exceed one roentgen in one hour at one meter from source except systems that operate in excess of five hundred kilovolts peak may have a leakage radiation at one meter from the source equivalent to the exposure within one hour of the useful beam at one meter from the source multiplied by a factor of one-thousandths.
- b. Permanent beam-limiting devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.
- c. Removable and adjustable beam-limiting devices.
- (1) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by ~~these~~ the useful devices, transmit not more than one percent of the ~~original~~ X-ray beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

- (2) Adjustable beam-limiting devices installed after ~~the effective date of this section~~ October 1, 1982, shall meet the requirements of paragraph 1.
- (3) Adjustable beam-limiting devices installed before ~~the effective date of this section~~ October 1, 1982, shall, for the portion of the X-ray beam to be blocked by these devices, transmit not more than five percent of the original X-ray beam at the maximum kilovoltage and maximum treatment filter.
- d. Filter system. The filter system shall be so designed that:
- (1) Filters cannot be accidentally displaced from the useful beam at any possible tube orientation.
- (2) Each filter is marked as to its material of construction and its thickness ~~or wedge angle for wedge filters~~. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- ~~(3) It shall be possible for the operator to determine the presence or absence of each filter and the orientation of each wedge filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation.~~
- ~~(4)~~ (3) The radiation at five centimeters from the filter insertion slot opening does not exceed thirty roentgens per hour under any operating conditions.
- e. Tube immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.
- f. Focal spot marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
- g. Beam block. Contact therapy tube housing assemblies shall have a removable shield of at least five-tenths millimeter lead equivalency at one hundred kilovolts peak that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- h. Beam monitor system. Systems of greater than one hundred fifty kilovolts peak manufactured after ~~the effective date of this section~~ October 1, 1982, shall be provided with a beam monitor system which:

- (1) Shall include a transmission detector which is a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;
- (2) (1) Shall have the detector of the monitor system interlocked to prevent incorrect positioning in the useful beam;
- (3) (2) Shall not allow irradiation until a preselected value of exposure of roentgens has been made at the treatment control panel;
- (4) (3) Shall independently terminate irradiation when the preselection number of roentgens has been reached;
- (5) (4) Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
- (6) (5) Shall have ~~the~~ a display at the control panel from which ~~reading in roentgens~~ the dose at a reference point in the treatment volume can be calculated;
- (7) (6) Shall have a control panel display which maintains the reading until intentionally reset to zero; and
- (8) (7) Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

i. Timer.

- (1) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a preset time selector and an elapsed time indicator.
- (2) The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the preset time selector through zero time.
- (3) The timer shall terminate irradiation when a preselected time has elapsed.

- (4) The timer shall permit accurate presetting and determination of exposure times as short as one second.
 - (5) The timer shall not permit an exposure if set at zero.
 - (6) The timer shall comply with the provisions of subdivision m of this subsection where applicable.
 - (7) The timer shall not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.
- j. Control panel functions. The control panel, in addition to the displays required in other provisions of this section shall have:
- (1) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;
 - (2) An indication of whether X-rays are being produced;
 - (3) Means for indicating kilovolts and X-ray tube current;
 - (4) The means for terminating an exposure at any time;
 - (5) A locking device which will prevent unauthorized use of the X-ray system; and
 - (6) For X-ray equipment manufactured after ~~the effective date of this section~~ October 1, 1982, a positive display of specific filters in the beam.
- k. Multiple tubes. When a control panel may energize more than one X-ray tube:
- (1) It shall be possible to activate only one X-ray tube during any time interval;
 - (2) There shall be an indication at the control panel identifying which X-ray tube is energized; and
 - (3) There shall be an indication at the tube housing assembly when that tube is energized.
- l. ~~Source-to-patient~~ Source-to-skin distance. There shall be means of determining the ~~source-to-patient~~ source-to-skin distance to within one centimeter.

- m. Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,
 - (1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
 - (2) An indication of shutter position shall appear at the control panel.
 - n. Low filtration X-ray tubes. Each X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
2. Facility design requirements for systems capable of operating above fifty kilovolts peak. In addition to shielding adequate to meet requirements of chapters 33-10-04 and 33-10-06, the treatment room shall meet the following design requirements:
- a- ~~Warning lights.~~ Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on".
 - b- a. Voice communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.
 - e- b. Viewing systems. Windows, mirrors, or closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means, e.g., television, an alternate viewing system shall be available for use in the event of electronic failure.
 - d- c. Additional requirements. Treatment rooms which contain an X-ray system capable of operating above one hundred fifty kilovolts peak shall meet the following additional requirements:
 - (1) All necessary shielding, except for any beam interceptor, shall be provided by fixed barriers.

- (2) The control panel shall be outside the treatment room.
- (3) All doors of the treatment room shall be electrically connected to the control panel such that X-ray production cannot occur unless all doors are closed. Entrance interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- (4) When ~~the doors~~ any door referred to in paragraph 3 ~~are~~ of this subdivision is opened while the X-ray tube is activated:
 - (a) X-ray production shall terminate within one second; or
 - (b) The radiation at a distance of one meter from the source shall be reduced to less than one hundred milliroentgens per hour within one second.
- ~~(5)~~ After the radiation output of the X-ray tube has been affected by the opening of any door referred to in paragraph 3, it shall be possible to restore the X-ray system to full operation only upon:
 - ~~(a) Closing the door, and subsequently,~~
 - ~~(b) Reinitiating the exposure at the control panel.~~

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

a. Surveys.

- (1) All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- (2) The expert shall report one's findings in writing to the person in charge of the facility and a copy of the report shall be maintained by the registrant for inspection by the department.

- (3) The survey and report shall indicate all instances where the installation in the opinion of the qualified expert is in violation of applicable regulations this article and cite all items of noncompliance.

b. Calibration.

- (1) The calibration of an X-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
- (2) The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.
- (3) Calibration of the radiation output of an X-ray system shall be performed with a calibration instrument calibrated dosimetry system. The calibration of such instrument system shall be directly traceable to a national standard. The instrument shall have been calibrated within the preceding two years.
- (4) The calibrations made pursuant to this subdivision shall be such that the dose at the reference point in soft tissue can be calculated to within ± five percent.
- (5) The calibration of the X-ray system shall include, but not be limited to, the following determinations:
 - (a) Verification that the X-ray system is operating in compliance with the design specifications.
 - (b) The exposure rates for each combination of field size, technique factors, filter, and treatment distance used.
 - (c) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present.
 - (d) An evaluation of the uniformity of the largest radiation field symmetry for the field sizes used and any dependence upon tube housing assembly orientation used.
- (6) Records of calibration performed pursuant to this subdivision shall be maintained by the

registrant for two years after completion of the calibration.

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

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

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

~~(2) The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the X-ray system.~~

~~(3) The spot check procedure shall specify the frequency at which tests or measurements are to be performed.~~

~~(4) The procedure shall also note conditions which shall require that the system be recalibrated in accordance with subdivision b.~~

~~(5) Records of spot check measurements performed pursuant to this subdivision shall be maintained by the registrant for two years following such measurement.~~

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

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

- (4) The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.
- (5) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot check procedures, the system shall be recalibrated as required in subdivision b of subsection 3 of section 33-10-06-08.
- (6) Records of spot check measurements shall be maintained by the registrant for two years after completion of the spot check measurements and any necessary corrective actions.
- (7) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 3 of section 33-10-06-08 or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

- (1) ~~Therapeutic~~ X-ray systems shall not be left unattended unless the system is secured pursuant to paragraph 5 of subdivision j of subsection i against unauthorized use.
- (2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
- (3) The tube housing assembly shall not be held by an individual during exposures hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed fifty kilovolts peak. In such cases, the holder shall wear protective gloves and apron of not less than five-tenths millimeter lead equivalency at one hundred kilovolts peak.
- (4) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of subsection 1 of section 33-10-04-02. No individual other than the patient shall be in the treatment room during exposures when the kilovolts peak exceeds one hundred fifty.

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

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. Definitions. In addition to the definitions provided in section 33-10-06-02, the following definitions are applicable to this section.
 - a. "Applicator" means a structure which indicated determines the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam-limiting device.
 - b. "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
 - c. "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the final first beam-limiting device.
 - d. "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.
 - e. "Dose monitor unit" means a unit from which the absorbed dose can be calculated.
 - f. "Existing equipment" means therapy systems subject to this section which were manufactured on or before August 1, 1980 January 1, 1985.
 - g. "Field flattening filter" means a filter used to homogenize the dose rate provide dose uniformity over the area of a useful beam of X-ray X-rays at a specified depth.
 - h. "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at a specific depth in a phantom and defined by

specified isodose lines the normal treatment distance and defined by the intersection of the major axes and the fifty percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

- i. "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
- j. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
- k. "Isocenter" means a fixed point in space located at the intersection of the rotation axis of the principal movements of the therapy system center of the smallest sphere through which the central axis of the beams passes in all conditions.
- l. "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.
- m. "New equipment" means systems subject to this section which were manufactured after ~~August 1, 1980~~ January 1, 1985.
- n. "Normal treatment distance" means the distance between the virtual source and a reference point on the central axis of the beam. The reference point is located at a position where the patient will be placed during radiation therapy.:
 - (1) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
 - (2) For X-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.
- o. "Patient" means an individual subjected to examination and treatment.
- p. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

- q. "Primary dose monitoring system" means a system which will monitor the quantity of radiation produced during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.
- r. "Radiation treatment prescription" means the absorbed dose which is intended to be delivered to the treatment volume.
- s. r. "Radiation head" means the structure from which the useful beam emerges.
- t. s. "Redundant dose monitoring combination" means a combination of two dose monitoring systems in which both systems are arranged to terminate irradiation in accordance with a preselected number of dose monitor units.
- u. t. "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.
- v. u. "Shadow tray" means a device attached to the radiation head to support auxiliary beam-limiting material.
- w. v. "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and patient during radiation.
- x. w. "Target" means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.
- y. x. "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
- z. y. "Treatment field" means the area of the patient's skin which is to be irradiated.
- aa. z. "Virtual source" means a point from which radiation appears to originate.

2. Requirements for equipment.

a. Leakage radiation to the patient area.

(1) New equipment shall meet the following requirements:

- (a) For all operating conditions, the absorbed dose equivalent in rem rads due to leakage

radiation, including X-rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or the normal treatment distance and outside the maximum useful beam, shall not exceed one-tenth percent of the maximum absorbed dose equivalent in rem rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters.

- (b) For each system the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subparagraph a for specified operation conditions. Records on leakage radiation shall be maintained at the installation for inspection by the department.
- (2) Existing equipment shall meet the following requirements:
- (a) The leakage radiation, excluding neutrons, at any point in the area specified by subparagraph a of paragraph 1 where such area intercepts the central axis of the beam one meter from the virtual source, shall not exceed one-tenth percent of the maximum dose equivalent at the point of intersection of the central axis of the beam and the surface of the referenced circular plane. Measurements shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified. For operating conditions producing maximum leakage radiation, the absorbed dose in rads due to leakage radiation excluding neutrons at any point in a circular plane of two meters radius centered on a perpendicular to the central axis of the beam one meter from the virtual source, and outside the maximum size useful beam, may not exceed one-tenth percent of the maximum absorbed dose in rads of the unattenuated useful beam measured

at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified.

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

b. Leakage radiation outside the patient area.

- (1) ~~The dose equivalent in rem due to leakage radiation, except in the area specified in subparagraph a of paragraph 1 of subdivision a, when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed one-tenth percent of X-ray leakage nor five-tenths percent for neutron leakage of the maximum dose equivalent in rem of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in subparagraph a of paragraph 1 of subdivision a of this subsection.~~ The absorbed dose in rads due to

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

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

c. Beam-limiting devices. Adjustable or interchangeable beam-limiting devices shall be provided and such devices shall transmit no more than two percent of the useful beam for the portion of the useful beam which is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement. Measurements shall be averaged over an area up to, but not exceeding, one hundred square centimeters at the normal treatment distance.

d. Filters.

(1) If the absorbed dose rate information required by subdivision p relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

(2) In systems which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

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

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

(c) An indication of the wedge filter orientation with respect to the treatment field shall be provided at the control panel, by direct observation or by electronic means, when wedge filters are used;

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

(e) Each filter which is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the wedge angle for wedge filters; and

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

filter selection operation carried out
at the treatment control panel:

- (1) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
 - (2) If the absorbed dose rate data required by subdivision p of subsection 2 of section 33-10-06-04 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
 - (3) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
 - (a) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - (b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - (c) A display shall be provided at the treatment control panel showing the filters in use; and
 - (d) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- e. Beam quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:
- (1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the value stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

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

- (2) Compliance with paragraph 1 of this subdivision shall be determined using:
- A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
 - The largest field size available which does not exceed fifteen centimeters by fifteen centimeters; and
 - A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.
- (3) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during X-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

Table IV

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

- (4) Compliance with paragraph 3 of this subdivision shall be determined by:
- (a) Measurements made within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
 - (b) Use of a phantom whose size and placement meet the requirements of paragraph 2 of this subdivision;
 - (c) Removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
 - (d) The largest field size available which does not exceed fifteen centimeters by fifteen centimeters.
- (5) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.
- f. Beam monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
- (1) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two monitoring systems ~~arranged either as a primary/primary combination or as a primary/secondary combination.~~
 - (2) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary system.
 - (3) The detectors and system into which the detector is incorporated shall meet the following requirements:
 - ~~(a) Each primary system shall have a detector which is a transmission detector and a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter.~~
 - ~~(b) The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning.~~
 - ~~(c) Each detector shall be capable of independently monitoring and controlling the useful beam.~~

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

(e) For new equipment the design of the dose monitoring systems of subparagraph d shall assure that the malfunctioning of one system shall not affect the correct functioning of the second system. In addition:

{1} The failure of any element which may be common to both systems shall terminate the useful beam.

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

(f) Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:

{1} Maintain a reading until intentionally reset to zero,

{2} Have only one scale and no scale multiplying factors in new equipment, and

{3} Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all normal conditions of use or foreseeable failures.

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

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

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

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

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

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

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

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

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

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

[4] In the event of power failure, the dose monitoring information required in this subparagraph displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty-minute period of time.

~~(g)~~ (f) In the event of power failure, the dose monitoring information required in subparagraph ~~f~~ e displayed at the control panel at the time of failure shall be retrievable in at least one system.

g. Beam symmetry.

(1) For new equipment, each therapy machine shall have the capability of comparing the dose rates in each of the four quadrants of the central eighty percent of the useful beam. Beam symmetry information shall be displayed at the treatment control panel, and such display shall be capable of indicating a differential

of more than five percent between any two of the quadrant dose rates. Beam asymmetry in excess of twenty percent shall automatically terminate the useful beam.

- (2) Beam symmetry requirements of paragraph 1 of this subdivision shall be met if the user can demonstrate to the satisfaction of the department that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator.
- (3) On existing equipment where the department has determined that beam symmetry is inadequate the use of an automatic beam asymmetry warning system may be required.

h. Selection and display of dose monitor units.

- (1) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
- (2) After useful beam termination, it shall be necessary to manually reset the preselected dose monitor units dosimeter display to zero before treatment can be reinitiated.
- (3) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.
- (4) For new equipment after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

i. Termination of irradiation by the dose monitoring system.

- (1) Each of the required monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.
- (2) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
- (3) Each secondary system shall terminate irradiation when one hundred two percent of the preselected number of dose monitor units has been detected by the system.

- (4) For new equipment, indicators on the control panel shall show which monitoring system has terminated the beam.
- j. Interruption switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, the equipment shall move to termination condition irradiation and equipment movements shall be automatically terminated.
- k. Termination switches. It shall be possible to terminate irradiation and equipment movements; or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.
- l. Timer.
- (1) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and decimals of minutes. The timer shall have a preset time selector and an elapsed time indicator.
- (2) The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero and subsequently reset the elapsed time indicator and the preset time selector after irradiation is terminated before irradiation shall again be possible.
- (3) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitor systems fail to do so. For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.
- m. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following requirements:
- (1) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

- (2) An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.
 - (3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - (4) An interlock system shall be provided to prevent irradiation with X-rays when electron applicators are fitted and irradiation with electrons when accessories specific for X-ray therapy are fitted.
 - (5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted.
 - (6) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- n. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
- (1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 - (2) An interlock system shall be provided to ensure that the equipment can emit only the energy of radiation which has been selected.
 - (3) ~~An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.~~
 - (4) (3) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
 - (4) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the X-ray target or electron window deviates by more than twenty percent or three megaelectron volts, whichever is smaller, from the selected nominal energy.

- o. Selection of stationary beam therapy or moving beam therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- (1) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
 - (2) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.
 - (3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - ~~(4) An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy.~~
 - ~~(5) Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained.~~
 - ~~(6) The mode of operation shall be displayed at the treatment control panel.~~
 - (4) The mode of operation shall be displayed at the treatment control panel.
 - (5) For new equipment, an interlock system shall be provided to terminate irradiation if:
 - (a) Movement of the gantry occurs during stationary beam therapy; or
 - (b) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
 - (6) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - (a) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than twenty percent from the selected value.

- (b) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.
- (7) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by subsection 1 of this section.
- p. Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated (the radiation detectors specified in subdivision f of subsection 2 of section 33-10-06-09 may form part of this system). In addition:
- (1) The quotient of the number of dose monitor units by time unit rate shall be displayed at the treatment control panel.
 - (2) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be a record maintained by the registrant.
- q. Location of foetal spot virtual source and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
- (1) The X-ray target or the virtual source of X-rays.
 - (2) The electron window or the scattering foil virtual source of electrons if the system has electron beam characteristics.
 - (3) All possible orientations of the useful beam.
- r. System checking facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

- s- Shadow trays shall be designed such that the skin entrance dose due to electrons produced within the shadow tray are minimized.
3. Facility and shielding requirements. In addition to chapter 33-10-04, the following design requirements shall apply:
- a. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers.
 - b. The treatment control panel shall be located outside the treatment room.
 - c. Windows, mirrors, closed-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the viewing system is by electronic means, e.g., television, an alternate viewing system shall be provided for use in the event of failure of the primary system.
 - d. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel. However, where excessive noise levels makes aural communication impractical other methods of communication shall be used.
 - e. Treatment rooms to which access is possible through more than one entrance room entrances shall be provided with warning lights, which will indicate when the useful beam is "on" in a readily observable position near the outside of all access doors.
 - f. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.
4. Surveys, calibrations, spot checks, and operating procedures.
- a. Surveys.
 - (1) All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

- (2) The registrant shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the registrant to the department within thirty days of receipt of the report.
- (3) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of ~~applicable regulations~~ this article and shall cite the section violated.

b. Calibrations.

- (1) The calibration of systems subject to ~~this~~ section 33-10-06-09 shall be performed before the system is first used for irradiation of patient and thereafter at time intervals which do not exceed ~~six~~ twelve months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.
- (2) The calibration shall be performed under the direct supervision of a qualified expert radiological physicist who is physically present at the facility during the calibration.
- (3) Calibration of the dose equivalent of the therapy beam shall be performed with a measurement instrument the calibration of which is directly traceable to national standards of exposure or absorbed dose and which shall have been calibrated within the preceding two years.
- (4) Calibrations made pursuant to subdivision b of this subsection shall be such that the dose at a reference point in soft tissue can be calibrated within ± five percent.
- (5) The calibration of the therapy beam shall include but be not limited to the following determinations:
 - (a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the sidelight and back-pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths.
 - (b) The exposure rate ~~or dose rate in air and~~ at various depths of water for the range of

field sizes used, for each effective energy, and for each treatment distance used for radiation therapy.

- (c) The congruence between the radiation field and the field indicated by the localizing device.
 - (d) The uniformity of the radiation field and its dependency upon the direction of the useful beam.
 - (e) The calibration determinations above shall be provided in sufficient detail such that the absorbed dose to issue in the useful beam may be calculated to within + five percent. Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
 - (f) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.
- (6) Records of the calibration performed pursuant to paragraph 1 of this subdivision shall be maintained by the registrant for two years after completion of the calibration.
- (7) A copy of the latest calibration performed pursuant to paragraph 1 of this subdivision shall be available for use by the operator at the treatment control panel.
- c. Spot checks. Spot checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:
- (1) ~~The spot check procedures shall be in writing and shall have been developed by a qualified expert.~~
 - (2) ~~The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure.~~

- (3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed.
 - (4) For systems in which beam quality can vary significantly, spot checks shall include quality checks.
 - (5) Where a system has built-in devices which provide a self-check of any parameter during irradiation, the spot check procedures shall require that the parameter be independently verified at specific time intervals.
 - (6) The reasons for spot checks which are erratic or inconsistent with calibration data shall be promptly investigated and corrected before the system is used for patient irradiation.
 - (7) Whenever a spot check indicates a significant change, as specified in the qualified expert's spot check procedures, in the operation characteristics of a system, the system shall be recalibrated as required in subdivision b.
 - (8) Records of spot check measurements performed pursuant to subdivision e shall be maintained by the registrant for a period of one year.
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- (1) The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the department prior to its implementation.
 - (2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within fifteen days.
 - (3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.
 - (4) At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.

- (5) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement may not be utilized as a spot check measurement.
- (6) The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
- (7) Whenever a spot check indicates a significant change in operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated as required in subdivision b of subsection 4 of this section.
- (8) Records of spot check measurements shall be maintained by the registrant for a period of two years after completion of the spot check measurements and any necessary corrective actions.
- (9) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 4 of this section or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

- (1) No individual other than the patient shall be in the treatment room during treatment of a patient.
- (2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
- (3) The system shall not be used in the administration of radiation therapy unless subdivisions a, b, and c of this subsection have been met.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-06-10. Veterinary medicine radiographic installations. In addition to the requirements of sections 33-10-06-03 and 33-10-06-04, the following regulations shall apply to all veterinary medicine radiographic installations:

1. Equipment.

- a. The protective tube housing shall be of diagnostic type.
 - b. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.
 - c. The total filtration permanently in the useful beam shall not be less than five-tenths millimeters aluminum equivalent for machines operating up to fifty kilovolts peak, one and one-half millimeters aluminum equivalent for machines operating between fifty and seventy kilovolts peak, and two and one-half millimeters aluminum equivalent for machines operating above seventy kilovolts peak.
 - d. A device shall be provided to terminate the exposure after a preset time or exposure.
 - e. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet [1.83 meters] from the animal during all X-ray exposures.
2. Structural shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers as required in Appendix C of this chapter.
 3. Operating procedures.
 - a. The operator shall stand well away from the useful beam and the animal during radiographic exposures.
 - b. No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required.
 - c. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and the individual shall be so positioned that no part of the individual's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-07-01. Scope. The requirements of this chapter apply to all licensees who use sealed sources in the healing arts and, are in addition to, ~~and not in substitution for,~~ other applicable requirements of this article.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

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

1. "Brachytherapy" means a method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver a beta or gamma radiation at a distance of up to a few centimeters [inches], by surface, intracavitary, or interstitial application.
2. "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

History: Effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-07-02. Interstitial, intracavitary, and superficial applications.

1. Accountability, storage and transit.
 - a. Except as otherwise specifically authorized by the department each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources. A physical inventory shall be made at least every ~~six~~ three months and a written record of the inventory maintained.
 - b. When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of subsections 1, 4, and 5 of section 33-10-04-02.
 - c. Each licensee shall follow the radiation safety and handling instructions approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and

maintain such instruction in a legible and conveniently available form.

- d. Each licensee shall assure that needles or standard medical applicator cells containing cobalt-60 as wire, radium-226, or cesium-137 are not opened while in the licensee's possession unless specifically authorized by a license issued by the department.

2. Testing sealed sources for leakage and contamination.

- a. All sealed sources with a half-life greater than thirty days and in any form other than gas shall be tested for leakage or contamination, or both, prior to initial use and at intervals not to exceed six months. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use. All sealed sources, containing more than one hundred microcuries of radioactive material with a half-life greater than thirty days, or ten microcuries of radium-226, shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state and described by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer.
- b. Leak tests shall be capable of detecting the presence of five-thousandths microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of one-thousandths microcurie per twenty-four hours. Any test conducted pursuant to subdivision a which reveals the presence of five-thousandths microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of one-thousandths microcurie or more per twenty-four hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of chapter 33-10-04. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might

expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department.

- c. Leak test results shall be recorded in units of microcuries and maintained for inspection by the department. Any leak test conducted pursuant to subdivision a of this subsection which reveals the presence of five-thousandths microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of one-thousandth microcurie per twenty-four hours, shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with department rules. A report shall be filed within five days of the test with the department describing the equipment involved, the tests results, and the corrective action taken.

3. Radiation surveys.

- a. The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation **and preferably by both.** This radiation level shall be entered on the patient's chart and signs as required under subsection 4 of this section.
- b. The radiation levels in the patient's room and the surrounding area shall be determined, recorded, and maintained for inspection by the department.
- c. The licensee shall assure that patients treated with cobalt-60, cesium-137, iridium-192, or radium-226 implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.

4. Signs and records.

- a. In addition to the requirements of subsection 3 of section 33-10-04-03, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual or individuals to contact for radiation safety instructions. The sign is not required provided the exception in subdivision b of subsection 4 of section 33-10-04-03 is met.

- b. The following information shall be included in the patient's chart:
- (1) The radionuclide administered, number of sources, activity in millicuries and time and date of administration.
 - (2) The exposure rate at one meter, the time the determination was made, and by whom.
 - (3) The radiation symbol.
 - (4) The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under subsection 1 of section 33-10-04-02.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-07-03. Teletherapy.

1. Equipment.

- a. The housing shall be so constructed that, at one meter from the source, the maximum exposure rate does not exceed ten milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each one meter from the source, shall not exceed two milliroentgens per hour.
- b. For teletherapy equipment installed after April 4, 1977, the leakage radiation measured at one meter from the source when the beam control mechanism is in the "on" position shall not exceed one-tenth of one percent of the useful beam exposure rate.
- c. Adjustable or removable beam-defining diaphragms shall allow transmission of not more than five percent of the useful beam exposure rate.
- d. The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.
- e. The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and

shall stay in the "off" position until activated from the control panel.

- f. When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.
 - g. There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off.
 - h. The equipment shall be provided with a locking device to prevent unauthorized use.
 - i. The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.
 - j. Provision shall be made to permit continuous observation of patients during irradiation.
 - k. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition. The monitoring device shall be equipped with a backup battery power supply for emergencies due to electrical power failures.
2. Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.
3. Testing for leakage and contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in subsection 2 of section 33-10-07-02. Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.
4. Calibration and physical decay determinations.
- a. Full calibration measurements shall be performed by licensees on each teletherapy unit:
 - (1) Prior to the first use of the unit for treating humans.
 - (2) Prior to treating humans:
 - (a) Whenever spot check measurements indicate that the output value differs by more than five

percent from the value obtained at the last full calibration corrected mathematically for physical decay;

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

(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. Full calibration measurements shall include determination of:

(1) The exposure rate or dose rate to an accuracy within \pm three percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

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

(4) Timer accuracy; and

(5) The accuracy of all distance measuring devices used for treating humans.

c. Full calibration measurements shall be made in accordance with the procedures recommended by the scientific committee on radiation dosimetry of the American association of physicists in medicine (Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396).

d. The exposure rate or dose rate values shall be corrected mathematically for physical decay for intervals not exceeding one month.

e. Full calibration measurements and physical decay corrections shall be performed by an expert qualified by training and experience in accordance with subdivision a of subsection 7.

5. Spot check measurements.

a. Spot check measurements shall be performed on each teletherapy unit at intervals not exceeding one month.

- b. Spot check measurements shall include determination of:
 - (1) Timer accuracy;
 - (2) The congruence between the radiation field and the field indicated by the light beam localizing device;
 - (3) The accuracy of all distance measuring devices used for treating humans;
 - (4) The exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and
 - (5) The difference between the measurement made in 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. Spot check measurements shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with subdivision a of subsection 7. (A qualified expert need not actually perform the spot check measurements.) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within fifteen days.

6. Dosimetry system calibration.

- a. Full calibration measurements shall be performed using a dosimetry system that has been calibrated by the national bureau of standards or by a regional calibration laboratory accredited by the American association of physicists in medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
- b. Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with subdivision a of this subsection. Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with subdivision a of this subsection. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

7. Qualified expert.

a. The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot check measurements. The licensee shall determine that the qualified expert:

a- (1) Is certified by the American board of radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma-ray physics, or X-ray and radium physics; or

b- (2) Has the following minimum training and experience:

(1) (a) A master's or doctor's degree in physics, biophysics, radiological physics or health physics;

(2) (b) One year of full-time training in therapeutic radiological physics;

(3) (c) One year of full-time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit; and

(4) (3) Licensees that have their teletherapy units calibrated by persons who do not meet criteria for minimum training and experience may request a license amendment excepting them from this subsection. The request should include the name of the proposed qualified expert, a description of the proposed expert's training and experience including information similar to that specified in this subdivision, reports of at least one calibration and spot check program based on measurements personally made by the proposed expert within the last ten years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American board of radiology in one of the specialties listed in subdivision a.

8. The licensee shall maintain, for inspection by the department, records of the measurements, tests, corrective actions, and instrument calibration made under subsections 4 and 5 and records of the licensee's evaluation of the qualified expert's training and experience made under subsection 7.

a. Records of (1) full calibration measurements, and (2) calibration of the instruments used to make these measurements shall be preserved for five years after completion of the full calibration.

- b. Records of ~~(1)~~ spot check measurements and corrective actions, and ~~(2)~~ calibration of instruments used to make spot check measurements shall be preserved for two years after completion of the spot check measurements and corrective actions.
- c. Records of the licensee's evaluation of the qualified expert's training and experience shall be preserved for five years after the qualified expert's last performance of a full calibration of the licensee's teletherapy unit.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-08-01. Purpose and scope. This chapter provides special requirements for analytical X-ray equipment. ~~The requirements of this chapter which are in addition to, and not in substitution for,~~ other applicable requirements of this article.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-08-02. Definitions.

1. "Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.
2. "Analytical X-ray system" means a group of local and remote components utilizing X-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.
3. "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
4. "Local components" means part of an analytical X-ray system and includes areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, ~~collimators~~ collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

5. "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.
6. "Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of the individual's body in the primary beam path during normal operation.
7. "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-08-03. Equipment requirements.

1. Safety device. A device which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the department for an exemption from the requirement of a safety device. Such application shall include:
 - a. A description of the various safety devices that have been evaluated.
 - b. The reason each of these devices cannot be used.
 - c. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operations operators and others in the area will be informed of the absence of safety devices.
2. Warning devices.
 - a. Open-beam configurations shall be provided with a readily discernible indication of:
 - a. (1) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner.

a. Each X-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of two and one-half millirem in one hour at any specified tube rating equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

b. Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of two and one-half millirems in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

8. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of one-quarter millirem in one hour.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-08-04. Area requirements.

1. Radiation levels. The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in subsection 5 of section 33-10-04-02. For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

2. Surveys.

a. Radiation surveys, as required by subsection 1 of section 33-10-04-03, of all analytical X-ray systems sufficient to show compliance with subsection 1 of this section shall be performed:

a- (1) Upon installation of the equipment, and at least once every twelve months thereafter.

b- (2) Following any change in the initial arrangement, number, or type of local components in the system.

- e- (3) Following any maintenance requiring the disassembly or removal of a local component in the system.
 - d- (4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed.
 - e- (5) Any time a visual inspection of the local components in the system reveals an abnormal condition.
 - f- (6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation protection guides (radiation dose limits).
- b. Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the department with subsection 1 in some other manner.
3. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT", or words having a similar intent.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-08-05. Operating requirements.

1. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No person shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.
2. Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.
3. Repair or modification of X-ray tube systems. Except as specified in subsection 2 of this section, no operation involving removal of covers, shielding materials, or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been

restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

4. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-08-06. Personnel requirements.

1. Instruction. No person shall be permitted to operate or maintain analytical X-ray equipment unless such person has received instruction in and demonstrated competence as to all of the following:
 - a. Identification of radiation hazards associated with the use of the equipment.
 - b. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases.
 - c. Proper operating procedures for the equipment.
 - d. Symptoms of an acute localized exposure.
 - e. Proper procedures for reporting an actual or suspected exposure.
2. Personnel monitoring.
 - a. Finger or wrist dosimetric devices shall be provided to and shall be used by:
 - a. (1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device.
 - b. (2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

- b. Reported dose values shall not be used for the purpose of determining compliance with subsection 1 of section 33-10-04-02 unless evaluated by a qualified expert.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-09-01. Purpose and scope.

1. This chapter establishes procedures for the registration and the use of particle accelerators.
2. In addition to the requirements of this chapter, all registrants are subject to the requirements of chapters 33-10-01, 33-10-02, 33-10-04, and 33-10-10. Registrants engaged in industrial radiographic operations are subject to the requirements of chapter 33-10-05 and registrants engaged in the healing arts are subject to the requirements of chapter 33-10-06 or 33-10-07, or both. Registrants engaged whose operations result in the production of radioactive material are subject to the requirements of chapter 33-10-03.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-09-02. Registration procedure.

1. Registration requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to this article or as otherwise provided for in this article. The general procedures for registration of particle accelerator facilities are included in chapter 33-10-02.
2. General requirements for the issuance of a registration for particle accelerators. (Refer to chapter 33-10-02.) In addition to the requirements of chapter 33-10-02, a registration application for use of a particle accelerator will be approved only if the department determines all of the following:
 - a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this chapter and chapters 33-10-04 and 33-10-10 in such a manner as to minimize danger to public health and safety or property.
 - b. The applicant's proposed or existing equipment, facilities, operating and emergency procedures are

adequate to protect health and minimize danger to public health and safety or property.

- c. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in subsection 3.
 - d. The applicant has appointed a radiation safety officer.
 - e. The applicant or the applicant's staff has substantial experience in the use of particle accelerators for the intended uses.
 - f. The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the department.
 - g. The applicant has an adequate training program for particle accelerator operators.
3. Human use of particle accelerators. In addition to the requirements set forth in chapter 33-10-02, a registration for use of a particle accelerator in the healing arts will be issued only if all of the following are met:
- a. Whenever deemed necessary by the department, the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation.
 - b. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.
 - c. The individual designated on the application as the user must be a physician.

History: Amended effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-09-03. Radiation safety requirements for the use of particle accelerators.

- 1. General provisions.

- a. This section establishes radiation safety requirements for the use of particle accelerators. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of the chapter.
 - b. The registrant shall be responsible for assuring that all requirements of this chapter are met.
2. Limitations.
- a. No registrant shall permit any person to act as a particle accelerator operator until such person shall have all of the following:
 - (1) Been instructed in radiation safety and shall have demonstrated an understanding thereof.
 - (2) Received copies of and instruction in this chapter and the applicable requirements of chapters 33-10-04 and 33-10-10, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof.
 - (3) Demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in the person's assignment.
 - b. Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.
3. Shielding and safety design requirements.
- a. A qualified expert, specifically accepted by the department, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.
 - b. Each particle accelerator installation shall be provided with such primary or secondary barriers as are necessary to assure compliance with subsections 1 and 5 of section 33-10-04-02.
4. Particle accelerator controls and interlock systems.
- a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

- b. All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.
 - c. When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console.
 - d. Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.
 - e. All safety interlocks shall be fail-safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.
 - f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.
5. Warning devices.
- a. All locations designated as high radiation areas, and entrances to such locations, shall be equipped with easily observable ~~flashing or rotating~~ warning lights that operate when, and only when, radiation is being produced.
 - b. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for fifteen seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and all radiation areas.
 - c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with subsection 3 of section 33-10-04-03.
6. Operating procedures.
- a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.
 - b. ~~Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off.~~ The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

- c. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three months. Results of such tests shall be maintained for inspection at the accelerator facility.
- d. Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the department and available to the operator at each accelerator facility.
- e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be all of the following:
 - (1) Authorized by the radiation safety committee or radiation safety officer.
 - (2) Recorded in a permanent log and a notice posted at the accelerator control console.
 - (3) Terminated as soon as possible.
- f. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

7. Radiation monitoring requirements.

- a. There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year, and after each servicing and repair.
- b. A radiation protection survey shall be performed and documented by a qualified expert specifically approved by the department when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.
- c. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a ~~remote and local~~ readout with ~~visual or audible~~ alarms at ~~both the control panel and at entrance to high radiation areas, and other appropriate locations, so that people entering or present become aware of the existence of the hazard.~~
- d. All area monitors shall be calibrated annually and after each servicing and repair.

- e. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present **in areas of airborne hazards.**
 - f. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination **in target and other pertinent areas.**
 - g. All area surveys shall be made in accordance with the written procedures established by a qualified expert, or the radiation safety officer of the particle accelerator facility.
 - h. Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.
8. Ventilation systems.
- a. Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of these limits specified in chapter 33-10-04, Appendix A, ~~Table II~~ Table I.
 - b. A registrant, as required by subsection 6 of section 33-10-04-02, shall not vent, release, or otherwise discharge airborne radioactive material to an **uncontrolled unrestricted** area which exceeds the limits specified in chapter 33-10-04, Appendix A, Table II, except as authorized pursuant to subsection 2 of section 33-10-04-04 or subdivision b of subsection 6 of section 33-10-04-02. For purposes of this subdivision, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to **uncontrolled unrestricted** areas, as far below these limits as practicable is reasonably achievable.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-10-01. Purpose and scope. This chapter establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with department inspections of licensees or registrants to ascertain compliance with the provisions of North Dakota Century Code chapter 23-20.1 **and regulations, this article,** orders, and licenses issued thereunder regarding radiological working conditions. This chapter applies to all persons who receive, possess, use, own, or transfer

material licensed by or registered with the department pursuant to chapters 33-10-02 and 33-10-03.

1. Posting of notices to workers.

- a. Each licensee or registrant shall post current copies of the following documents:
 - (1) This chapter and chapter 33-10-04.
 - (2) The license, certificate of registration, conditions, or documents incorporated into the license by reference and amendments thereto.
 - (3) The operating procedures applicable to work under the license or registration.
 - (4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to chapter 33-10-01, and any response from the licensee or registrant.
- b. If posting of a document specified in paragraph 1, 2, or 3 of subdivision a is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- c. Department Form RAD 681 "Notice to Employees" shall be posted by each licensee or registrant **wherever individuals work in or frequent any portion of a restricted area as required by this article.**
- d. Documents, notices, or forms posted pursuant to this subsection shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.
- e. Department documents posted pursuant to paragraph 3 4 of subdivision a shall be posted within two working days after receipt of the documents from the department. The licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

2. Instructions to workers. All individuals working in or frequenting any portion of a restricted area shall be kept

informed of the storage, transfer, or use of radioactive material or of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated with exposure to such radioactive material or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of department regulations this article and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of department regulations this article and licenses or unnecessary exposure to radiation or radioactive material; shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to subsection 3. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

3. Notifications and reports to individuals.

- a. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subsection. The information reported shall include data and results obtained pursuant to department regulations this article, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to department regulations this article. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of North Dakota State Radiological Health Regulations Rules (North Dakota Administrative Code chapter 33-10-10). You should preserve this report for further reference.

- b. At the request of any worker, each licensee or registrant shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to

subdivisions a and c of subsection 1 of section 33-10-04-05.

- c. At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within thirty days from the time the request is made, or within thirty days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the department; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.
 - d. When a licensee or registrant is required pursuant to subsection 5 of section 33-10-04-05 to report to the department any exposure of any individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the individual's exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the department.
 - e. At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's facility in that calendar quarter, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination a written report regarding the radiation dose received by the worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written statement of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.
4. Presence of representatives of licensees or registrants and workers during inspection.
- a. Each licensee or registrant shall afford to the department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to this article.

- b. During an inspection, department inspectors may consult privately with workers as specified in subsection 5. The licensee or registrant may accompany department inspectors during other phases of an inspection.
 - c. If, at the time of inspection, an individual has been authorized by the workers to represent them during department inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
 - d. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subsection 2.
 - e. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.
 - f. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany department inspectors during the inspection of physical working conditions.
 - g. Notwithstanding the other provisions of this subsection, department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.
5. Consultation with workers during inspections.
- a. Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of **department regulations** this article and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.
 - b. During the course of an inspection any worker may bring privately to the attention of the inspectors, either

orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of North Dakota Century Code chapter 23-20.1, this article, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. Any such notice, in writing, shall comply with the requirements of subdivision a of subsection 6.

- c. The provisions of subdivision b shall not be interpreted as authorization to disregard instructions pursuant to subsection 2.

6. Requests by workers for inspections.

- a. Any worker or representative of workers **who believes believing that a ~~violation~~ violations** of North Dakota Century Code chapter 23-20.1, this article, or license conditions **exists or has exist or have** occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of inspection except that, upon the request of the worker giving such notice, the worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the department, except for good cause shown.
- b. If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in subdivision a, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, **the department shall cause an inspection to** shall be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this subsection need not be limited to matters referred to in the complaint.
- c. No licensee **or, registrant, or contractor or subcontractor of a licensee or registrant** shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this article or has testified or is about to testify in any such proceeding or because of the exercise by such worker on

behalf of the worker or others of any option afforded by this chapter.

7. Inspections not warranted - informal review. -

- a. If the department determines, with respect to a complaint under subsection 6, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the department which will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the department which will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. The department shall render an informal opinion after the close of the conference. The complainant shall have the right of petition for a formal administrative hearing as provided for by North Dakota Century Code chapter 28-32 and department regulations North Dakota Administrative Code article 33-22, following the decision of such formal conference.
- b. If the department determines that an inspection is not warranted because the requirements of subdivision a of subsection 6 have not been met, the department shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of subdivision a of subsection 6.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-11-03. Exemptions. No application fees, license fees, amendment fees, renewal fees, or special project fees, shall be required for:

1. A license authorizing the use of source material as shielding only in devices and containers; provided, however, that all other licensed byproduct material, source material, or special nuclear material in the device or container will be subject to the fees prescribed in Appendix A of this chapter.
2. Agencies of the state of North Dakota shall be exempt from the fees prescribed in Appendix A of this chapter.
3. The department may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of this ~~part~~ chapter as it determines are authorized by law and are otherwise in the public interest.

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

General Authority: NDCC 28-32-02

Law Implemented: NDCC 23-20.1-04

33-10-11-04. Payment of fees.

1. License and registration fees. The appropriate licensing or registration fee shall accompany the application for licensure or registration when filed with the department.
2. Amendment fees. The appropriate amendment fee shall accompany the application for amendment when filed with the department.
3. Renewal fees. The appropriate renewal fee shall accompany the renewal application when filed with the department.
4. Reciprocity fee. The appropriate reciprocity fee shall accompany the written notification as required in section 33-10-03-06.
5. Special project fees. Fees for special projects are payable upon notification by the department when the review of the project is completed. Special projects mean those projects submitted to the department for review and for which specific fees are not prescribed in this chapter.
- ~~5-~~ 6. Method of payment. Fee payments shall be by check, draft, or money order made payable to the North Dakota state department of health.
- ~~6-~~ 7. Return of application and fee payment. The application for licensure or registration shall be accompanied by the fee payment and shall be submitted to:

**North Dakota State Department of Health
Fiscal Office
State Capitol Building
Bismarck, ND 58505**

North Dakota State Department of Health
Environmental Engineering
1200 Missouri Avenue
Box 5520
Bismarck, ND 58502-5520

History: Effective October 1, 1982; amended effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-04

STAFF COMMENT: Chapter 33-10-12 contains all new material but is not underscored so as to improve readability.

CHAPTER 33-10-12
RADIATION SAFETY REQUIREMENTS FOR WIRE LINE SERVICE OPERATIONS
AND SUBSURFACE TRACER STUDIES

Section	Purpose
33-10-12-01	Purpose
33-10-12-02	Scope
33-10-12-03	Definitions
33-10-12-04	Prohibition
33-10-12-05	Equipment Control
33-10-12-06	Requirement for Personnel Safety
33-10-12-07	Precautionary Procedures in Logging and Subsurface Tracer Operations
33-10-12-08	Radiation Surveys and Records
33-10-12-09	Notification - Incidents, Abandonment, and Lost Sources

33-10-12-01. Purpose. This chapter establishes radiation safety requirements for persons using sources of radiation for wire line service operations including mineral logging, radioactive markers, and subsurface tracer studies. The requirements of this chapter are in addition to the requirements of chapters 33-10-01, 33-10-02, 33-10-03, 33-10-04, and 33-10-10.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-02. Scope. This chapter applies to all licensees or registrants who use sources of radiation for wire line service operations including mineral logging, radioactive markers, or subsurface tracer studies.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-03. Definitions. As used in this chapter, the following definitions apply:

1. "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.
2. "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
3. "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
4. "Logging tool" means a device used subsurface to perform well logging.
5. "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.
6. "Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.
7. "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
8. "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well logging operations.
9. "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well bore or adjacent formation.
10. "Temporary jobsite" means a location to which radioactive materials have been dispatched to perform wire line service operations or subsurface tracer studies.
11. "Well bore" means a drilled hole in which wire line service operations and subsurface tracer studies are performed.
12. "Well logging" means that lowering and raising of measuring devices or tools which may contain sources of radiation into well bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

13. "Wire line" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well bore.
14. "Wire line service operation" means any evaluation or mechanical service which is performed in the well bore using devices on a wire line.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-04. Prohibition. No licensee may perform wire line service operations with a sealed source unless, prior to commencement of the operations, the licensee has a written agreement with the well operator, wellowner, drilling contractor, or landowner that:

1. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made.
2. In the event a decision is made to abandon the sealed source downhole, the requirements of subdivision c of subsection 1 of section 33-10-12-09 shall be met.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-05. Equipment control.

1. **Limits on levels of radiation.** Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of chapter 33-10-03 and the dose limitation requirements of chapter 33-10-04 are met.
2. **Storage precautions.**
 - a. Each source of radiation, except accelerators, shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.
 - b. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.
3. **Transport precautions.** Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.
4. **Radiation survey instruments.**

- a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this chapter and by subsection 1 of section 33-10-04-03. Instrumentation shall be capable of measuring one-tenth milliroentgen per hour through at least twenty milliroentgens per hour.
- b. Each radiation survey instrument shall be calibrated:
 - (1) At intervals not to exceed six months and after each instrument servicing.
 - (2) At energies and radiation levels appropriate for use.
 - (3) So that accuracy within plus or minus twenty percent of the true radiation level can be demonstrated on each scale.
- c. Calibration records shall be maintained for a period of two years for inspection by the department.

5. Leak testing of sealed sources.

- a. Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department for six months after the next required leak test is performed or until transfer or disposal of the sealed source.
- b. Method of testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of five-thousandths microcurie of radioactive material on the test sample.
- c. Interval of testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source may not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

- d. Leaking or contaminated sources. If the test reveals the presence of five-thousandths microcurie or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with this article. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the department.
- e. Exemptions. The following sources are exempt from the periodic leak test requirements of subdivisions a, b, c, and d of this subsection:
 - (1) Hydrogen-3 sources.
 - (2) Sources of radioactive material with a half-life of thirty days or less.
 - (3) Sealed sources of radioactive material in gaseous form.
 - (4) Sources of beta and/or gamma emitting radioactive material with an activity of one hundred microcuries or less.
 - (5) Sources of alpha emitting radioactive material with an activity of ten microcuries or less.
- 6. **Quarterly inventory.** Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records or 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 sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.
- 7. **Utilization records.** Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the department for two years from the date of the recorded event, showing the following information for each source of radiation:
 - a. Make, model number, and a serial number or a description of each source of radiation used.
 - b. The identity of the well-logging supervisor or field unit to whom assigned.
 - c. Locations where used and dates of use.

- d. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.
8. **Design, performance, and certification criteria for sealed sources used in downhole operations.**
- a. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after June 1, 1986, shall be certified by the manufacturer, or other testing organization acceptable to the department to meet the following minimum criteria:
 - (1) Be of doubly encapsulated construction.
 - (2) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical.
 - (3) Has been individually pressure tested to at least twenty-four thousand, six hundred fifty-six pounds per square inch absolute without failure.
 - b. For sealed sources, except those containing radioactive material in gaseous form, acquired after June 1, 1986, in the absence of a certificate from a transferor certifying that an individually sealed source meets the requirements of subdivision a, the sealed source shall not be put into use until such determinations and testing have been performed.
 - c. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after June 1, 1986, shall be certified by the manufacturer, or other testing organization acceptable to the department, as meeting the sealed source performance requirements for oil well logging as contained in the American national standard N542, Sealed Radioactive Sources, Classification in effect on June 1, 1986.
 - d. Certification documents shall be maintained for inspection by the department for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the department authorizes disposition.
9. **Labeling.**
- a. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER*
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

- b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER*
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

* or CAUTION

10. Inspection and maintenance.

- a. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the department.
- b. If any inspection conducted pursuant to subdivision a reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.
- c. The repair, opening, or 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, an agreement state, or a licensing state.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-06. Requirement for personnel safety.

1. Training requirements.

- a. No licensee or registrant may permit any individual to act as a logging supervisor until such individual has:
 - (1) Received, in a course recognized by the department, the United States nuclear regulatory commission, an

agreement state, or a licensing state, instruction in the subjects outlined in Appendix A of this chapter and demonstrated an understanding thereof.

- (2) Read and received instruction in the rules contained in this chapter and the applicable sections of chapters 33-10-01, 33-10-04, and 33-10-10 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof.
 - (3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- b. No licensee or registrant may permit any individual to assist in the handling of sources of radiation until such individual has:
- (1) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof.
 - (2) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- c. The licensee or registrant shall maintain employee training records for inspection by the department for two years following termination of employment.
2. **Operating and emergency procedures.** The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:
- a. Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in chapter 33-10-04.
 - b. Methods and occasions for conducting radiation surveys.
 - c. Methods and occasions for locking and securing sources of radiation.
 - d. Personnel monitoring and the use of personnel monitoring equipment.
 - e. Transportation to temporary jobsites and field stations, including the packaging and placing of sources of

radiation in vehicles, placarding the vehicles, and securing sources of radiation during transportation.

- f. Minimizing exposure of individuals in the event of an accident.
 - g. Procedure for notifying proper personnel in the event of an accident.
 - h. Maintenance of records.
 - i. Inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools.
 - j. Procedures to be followed in the event a sealed source is lodged downhole.
 - k. Procedures to be used for picking up, receiving, and opening packages containing radioactive material.
3. **Personnel monitoring.**
- a. No licensee or registrant may permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.
 - b. Personnel monitoring records shall be maintained for inspection until the department authorizes disposition.

History: Effective June 1, 1986.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-02

33-10-12-07. Precautionary procedures in logging and subsurface tracer operations.

- 1. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in chapter 33-10-01.
- 2. The licensee shall provide and require the use of tools that will assure remote handling or sealed sources other than low activity calibration sources.
- 3. a. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel

handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

- b. No licensee may cause the injection of radioactive material into potable aquifers without prior written authorization from the department.
4. No licensee or registrant may permit aboveground testing of particle accelerators, designed for use in well logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of subsections 1 and 5 of section 33-10-04-02, as applicable, are met.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-08. Radiation surveys and records.

1. Radiation surveys.

- a. Radiation surveys and/or calculations shall be made and recorded for each area where radioactive materials are stored.
- b. Radiation surveys and/or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and/or calculations shall include each source of radiation or combination of sources to be transported in the vehicle.
- c. After removal of the sealed source from the logging tool and before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.
- d. Radiation surveys shall be made and recorded at the jobsite or wellhead for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.
- e. Records required pursuant to subdivisions a and d shall include the dates, the identification of individuals making the survey, the identification of survey instruments used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the department for two years after completion of the survey.

2. **Documents and records required at field stations.** Each licensee or registrant shall maintain, for inspection by the department, the following documents and records for the specific devices and sources used at the field station:
 - a. Appropriate license, certificate of registration, or equivalent document.
 - b. Operating and emergency procedures.
 - c. Applicable chapters of this article.
 - d. Records of the latest survey instrument calibrations pursuant to subsection 4 of section 33-10-12-05.
 - e. Records of the latest leak test results pursuant to subsection 5 of section 33-10-12-05.
 - f. Quarterly inventories required pursuant to subsection 7 of section 33-10-12-05.
 - g. Utilization records required pursuant to subsection 7 of section 33-10-12-05.
 - h. Records of inspection and maintenance required pursuant to subsection 10 of section 33-10-12-05.
 - i. Survey records required pursuant to subsection 1 of this section.

3. **Documents and records required at temporary jobsites.** Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the department.
 - a. Operating and emergency procedures.
 - b. Survey records required pursuant to subsection 1 for the period of operation at this site.
 - c. Evidence of current calibration for the radiation survey instruments in use at the site.
 - d. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent documents.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-12-09. Notification - 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.
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 if radioactive contamination is detected at the surface or if the source appears to be damaged.
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 subdivision d of this subsection.
 - b. Notify the department by telephone, 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, setting forth the following information:
 - (1) Date of occurrence and a brief description of attempts to recover the source.
 - (2) A description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form.
 - (3) Surface location and identification of well.

- (4) Results of efforts to immobilize and set the source in place.
 - (5) Depth of the radioactive source.
 - (6) Depth of the top of the cement plug.
 - (7) Depth of the well.
 - (8) Information contained on the permanent identification plaque.
4. Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well bore. An example of a suggested plaque is shown in Appendix B of this chapter. This plaque shall:
- a. Be constructed of long-lasting material, such as stainless steel or monel.
 - b. Contain the following information engraved on its face:
 - (1) The word "CAUTION".
 - (2) The radiation symbol without the conventional color requirement.
 - (3) The date of abandonment.
 - (4) The name of the well operator or well owner.
 - (5) The well name and well identification numbers or other designation.
 - (6) The sealed sources by radionuclide and quantity of activity.
 - (7) The source depth and the depth to the top of the plug.
 - (8) An appropriate warning, depending on the specific circumstances of each abandonment. Appropriate warnings may include: (a) "Do not drill below plug back depth;" (b) "Do not enlarge casing;" or (c) "Do not reenter the hole", followed by the words, "before contacting the North Dakota State Department of Health".
5. The licensee shall immediately notify the department by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water

source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

History: Effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

SEPTEMBER 1986

33-18-01-02. Definitions. For the purpose of this chapter, the following definitions shall apply:

1. "Abandoned well" means a well whose use has been permanently discontinued.
2. "Annular space" means the opening between a well hole excavation and the well casing or curb, or between a casing pipe and a liner pipe.
3. "Appurtenances" means valves, meters, taps, gauges, or other devices required for adequate control or measurement of the well output.
4. "Aquifer" means a water-bearing formation that transmits water in sufficient quantities to supply a well.
5. "Casing" shall mean the pipe installed in the drill hole to give unobstructed access to the water-bearing formation.
6. "Constructing" a well includes boring, digging, drilling, or excavation in installing casings, well screens, and other appurtenances.
7. "Contamination" means alteration of the physical, chemical, or biological quality of the water so that it is harmful or potentially injurious to the health of the users or for the intended use of the water.
8. "Department" means the North Dakota state department of health.
9. "Disinfection" means the killing of infectious agents outside the body by chemical or physical means.

10. "Drawdown" means the extent of lowering the water surface in a well and of the water table adjacent to the well, resulting from the discharge of water from the well by pumping or natural flow.
11. "Drilling" means making any opening in the earth's surface by drilling, boring, or otherwise, and includes inserting any object into any part of the earth's surface for the purpose of obtaining an underground water supply except drainage tiles or similar devices designed primarily to improve land by removing excess water.
12. "Established ground surface" means the permanent elevation of the surface of the ground at the site of the well.
13. "Ground water source" means all water obtained from dug, drilled, bored, or driven well, infiltration lines, and springs.
14. "Grout" or "grouting material" means any stable impervious bonding material which is capable of providing a watertight seal between the casing and the formation throughout the depth required to protect against objectionable matter and which is reasonably free of shrinkage.
15. "Liner pipe" means a pipe installed inside a completed and cased well for the purpose of sealing off undesirable water or for repairing ruptured or punctured casing or screens.
16. "Pitless unit" is an assembly designed for attachment to a well casing which permits buried pump discharge from the well and allows access to the interior of the well casing for installation or removal of the pump or pump appurtenances. "Pitless adapter" means a device assembled at the well site for attachment to one or more openings through the well casing and is so constructed as to prevent the entrance of contaminants into the well or potable water supply, conduct water from the well below the frostline to prevent freezing, and provide full access to the water system components within the well.
17. "Pitless unit" means a factory-assembled device with cap which extends the upper end of a well casing to above grade and is so constructed as to prevent the entrance of contaminants into the well or potable water supply, conduct water from the well below the frostline to prevent freezing, and provide full access to the well and the water system components within the well.
18. "Potable water" means water free from impurities in amounts sufficient to cause disease or harmful physiological effects, with the bacteriological and chemical quality conforming to applicable standards.

- ~~18-~~ 19. "Private water supply" means one that is not for public use.
20. "Pressure tank" or "hydropneumatic tank" means a closed water storage container constructed to operate under a designed pressure rating to modulate the water system pressure within a selected range.
- ~~19-~~ 21. "Public water supply" means a water supply connected to at least fifteen service connections or regularly serves an average of twenty-five persons daily, sixty days out of the year.
- ~~20-~~ 22. "Pumps" and "pumping equipment" means any equipment or materials utilized or intended for use in withdrawing or obtaining ground water for any use, including, without limitation, seals and tanks, together with fittings and controls.
- ~~21-~~ 23. "Repair" means any action which results in a breaking or opening of the well seal or replacement of a pump.
- ~~22-~~ 24. "Shall" means mandatory compliance with all aspects of the rules and regulations for water well construction and water well pump installation.
- ~~23-~~ 25. "Should" means provisions which are not mandatory but which are recommended or desirable procedures or methods. Deviation from the rules and regulations for water well construction and water well pump installation is subject to individual consideration.
- ~~24-~~ 26. "Static water level" means the elevation of the surface of the water in a well when no water is being discharged therefrom.
- ~~25-~~ 27. "Water well contractor" means any person who is certified to conduct the business of well drilling under the provisions of North Dakota Century Code chapter 43-35.
28. "Water well pump and pitless unit installer" means any person who is certified to conduct the business of installing water well pumps and pitless units under the provisions of North Dakota Century Code chapter 43-35.
- ~~26-~~ 29. "Well seal" means an approved arrangement or device used to cap a well or to establish and maintain a junction between the casing or curbing of a well and the piping or equipment installed therein, the purpose or function of which is to prevent pollutants from entering the well at the upper terminal.
- ~~27-~~ 30. "Well vent" means an outlet at the upper terminal of the well casing to allow equalization of air pressure in the well and escape of toxic or inflammable gases.

~~28-~~ 31. "Wells" means any artificial opening or artificially altered natural opening however made by which ground water is sought or through which ground water flows under natural pressure or is artificially withdrawn; provided, that this definition does not include a natural spring, stock ponds, or holes drilled for the purpose of exploration for production of oil, gas, gravel, or other minerals.

History: Amended effective September 1, 1986.

General Authority: NDCC ~~28-32-02~~ 43-35-19, 43-35-19.1

Law Implemented: NDCC ~~28-32-02~~ 43-35-19, 43-35-19.1

33-18-01-05. Protection of ground water sources.

1. **Minimum protective depths of wells.** All wells shall be watertight to exclude contamination. Wells shall be designed to seal off formations that are or may be contaminated or undesirable.

Wells constructed in unconsolidated formations with stable overburdens cannot be expected to form a continuous contact seal. Unless approved otherwise by the department, the annular opening outside the casing shall be filled with neat cement grout or other approved material at least one and one-half inches [3.81 centimeters] in thickness to a depth of not less than twenty feet [6.1 meters]. Wells with a depth of twenty feet [6.1 meters] or less shall be grouted from the top of the well screen. Greater depths are preferable and may be required for specific installations as determined by review of the plans and specifications.

Driven well casing may, when conditions warrant, be installed without grouting.

2. **Required protection for various sources.**

- a. **Gravel wall wells.** The gravel used shall be free of foreign material, properly sized, washed, and then disinfected prior to or during placement. Where gravel refill pipes are used, their upper terminal shall be incorporated within the pump foundation and terminated with screwed or welded caps at least ~~thirteen~~ twelve inches [~~33-02~~ 30.48 centimeters] above the pumphouse floor or concrete apron.

The outer casing or drill hole shall be of such diameter as to provide a minimum of one and one-half inches [3.81 centimeters] of grout around the gravel refill pipes when installed in the grouted annular opening. Provisions for prevention of leakage of grout into the gravel pack or screen shall be provided.

- b. **Radial collector wells.** The location of all caisson construction joints and porthole assemblies shall be indicated. The caisson wall shall be substantially reinforced. Radial collectors shall be in areas and at depths approved by the department. Provisions shall be made to assure minimum vertical rise. The top of the caisson shall be covered with a watertight floor. All openings in the floor shall be curbed and protected from entrance of foreign material. Pump discharge piping shall not be placed through caisson walls.
- c. **Dug or bored wells.** Dug or bored wells shall be developed only where geological conditions preclude the development of a satisfactory drilled well.

Every dug or bored well shall have a continuous watertight ~~lining of steel casing or concrete.~~ The ~~lining~~ section of casing in the producing zone shall serve as the well screen, shall readily admit water, and shall be structurally sound to withstand external pressures.

The open space between the excavation and the installed ~~lining casing~~ shall be sealed with cement grout or other approved materials.

The watertight ~~lining casing~~ shall extend at least ~~eight~~ twelve inches [~~20-32~~ 30.48 centimeters] above finished ground surface. A cover slab at least four inches [10.16 centimeters] thick, adequately reinforced and having a diameter sufficient to overlap the lining by two inches [5.08 centimeters] shall be provided. The slab shall be constructed without joints.

The top of the slab shall be sloped to drain to all sides and a watertight joint made where the slab rests on the well ~~lining casing~~ using cement mortar or a mastic compound.

A manhole, if installed, shall be provided with a curb cast in the slab and extending at least four to six inches [10.16 to 15.24 centimeters] above the slab. The manhole shall have a watertight overlapping cover extending down around the curb by at least two inches [5.08 centimeters].

Adequate sized pipe sleeve or sleeves shall be cast in place in the slab to accommodate the type of pump or pump piping proposed for the well.

- d. **Infiltration wells.** Infiltration wells may be considered where geological conditions preclude possibility of developing an acceptable drilled well. The area around the well shall be under the control of the water purveyor for a distance acceptable to or required by the

department. The flow in the lines shall be by gravity to a collecting well. The water shall be continuously chlorinated to assure bacterial purity.

- e. **Flowing wells.** The construction of flowing wells shall be in compliance with North Dakota Century Code chapter 61-20.

The construction of flowing wells shall be such that the flow from them can be controlled. The drill hole shall extend into, but not through, the confining bed. A protective casing shall be installed, and the annular space grouted to form a tight seal. The grout should extend upward from within five feet [1.52 centimeters] of the top of the aquifer to the ground surface. After the grout has set, the drill hole may be extended into the artesian formation.

An inner casing shall be required where erosion of the confining bed by the flowing water will occur. This inner casing shall be joined in a watertight manner to the protective casing. Flow control should consist of valved pipe connections, watertight pump connections, or receiving reservoirs set at an elevation corresponding to the artesian head.

- f. **Existing wells.** The department shall be consulted for requirements concerning the reconstruction of existing wells.

History: Amended effective January 1, 1984; September 1, 1986.

General Authority: NDCC ~~28-32-02~~ 43-35-19, 43-35-19.1

Law Implemented: NDCC ~~28-32-02~~ 43-35-19, 43-35-19.1

33-18-01-06. General well construction requirements.

1. **Construction water.** Water used in the drilling process shall be obtained from a source which will not result in contamination of the well. Chlorination of the water with an initial dosage of not less than fifty milligrams per liter (one gallon [3.78 liters] of laundry bleach or 0.6 pounds [1.32 kilograms] of calcium hypochlorite per one thousand gallons [3.78 kiloliters] of drilling water) is ~~desirable~~ recommended.

Waters from surface sources must be chlorinated with a minimum dosage of one hundred milligrams per liter (two gallons [7.56 liters] of laundry bleach or 1.2 pounds [2.64 kilograms] of calcium hypochlorite per one thousand gallons [3.78 kiloliters] of drilling water).

2. **Ferrous well casing.**

- a. **General.** Casing and liner pipe of wrought iron or steel through ten inches [25.4 centimeters] in diameter shall be prime pipe meeting current American Society for Testing and Materials Schedule 40, or equivalent specifications. Larger diameter pipes shall have a minimum wall thickness of three hundred seventy-five thousandths of an inch [0.952 centimeters].

All casing shall have additional thickness and weight if standard thickness is not considered sufficient to assure reasonable life expectancy of the well or be capable of withstanding forces to which they are subjected.

- b. **Drive shoe.** Pipe that is to be driven shall be equipped with a drive shoe or other device approved by the department.
- c. **Joints.** Casing and liner pipe joints shall be properly welded or threaded.

3. **Nonferrous well casing.**

- a. **General.** Pipe other than wrought iron or steel must be adaptable to the stresses to which they will be subjected during installation and to the corrosiveness of the water.

- b. **Thermoplastic well casing.** Thermoplastic well casing shall conform with American Society for Testing and Materials Specification F480-81 or latest revision as follows:

(1) Minimum standard dimension ratio shall be twenty-one.

(2) Minimum pipe stiffness shall be two hundred twenty-four pounds foot/ (inch · inch) (kiloneutron/ (meter · meter)) when tested according to section 5.4.1 of American Society for Testing and Materials Specification F480.

(3) All casing five inches [12.7 centimeters] and larger shall be tested for impact resistance and meet or exceed IC-1 impact classification according to section 6.5 and table 6 of American Society for Testing and Materials Specification F480.

(4) Carry the seal of the national sanitation foundation.

All casing shall have additional thickness and weight if standard thickness is not capable of withstanding forces to which it is subject.

- c. **Poured-in-place concrete well casing.** Poured-in-place well casing shall be at least six inches [15.24

centimeters] thick and be poured in one operation if possible. There shall be no construction joint within ten feet [3.05 meters] of the original ground surface.

- d. **Other materials.** Other well casing materials that may be proposed shall be approved in writing by the department prior to installation.
4. **Packers.** Packers shall be of a material that will not impart taste, odors, toxic substances, or bacterial contamination to the water in the well. Lead packers may, under certain conditions when in contact with soft aggressive waters possessing sufficient plumbosolvency, result in toxic concentrations of lead in the water. When the water is to be used for domestic or livestock purposes, lead packers shall be restricted to use with nonaggressive waters and used only when nontoxic packers such as neoprene cannot be properly installed.
5. **Screens.** Screen openings shall provide the maximum amount of open area consistent with the strength of the screen and grading of the water-bearing formation or gravel pack. The size of the screen should be based on a sieve analysis. The openings shall permit maximum transmitting ability without clogging or jamming. Screens should be constructed of material which will not be damaged by chemical action of ground water or future cleaning operations and be installed so that exposure above pumping level will not occur. Lead shot, lead wool, or other toxic lead products shall not be used for sealing the bottom of well screens or casing.
6. **Yield and drawdown test.** Every well should be tested for yield and drawdown. The test method to be followed should be clearly outlined in the specifications. The test pump should have a maximum capacity at least equal to one and one-half times the quantity of water anticipated. The test pump should be able to operate continuously until the water level has stabilized. Test data to be recorded should include:
 - a. Static water level.
 - b. Pumping rate.
 - c. Drawdown during test.
 - d. Recovery water levels.
 - e. Depth of pump setting.

Duration of the test shall be determined with due consideration given to pumping of sand, clarity of water pumped, and the obtaining of a representative sample of water for chemical analysis.

7. **Chemical conditioning.** When chemical treatment of a public well is proposed, the method of conditioning shall be included in the specifications. The equipment, chemicals, and inhibitors to be used, the method of testing for chemical residuals and the disposal of waste shall be indicated.

8. **Grouting requirements.**

a. **Concrete grout.** The mixture should consist of cement, sand, and water, in the proportion of one bag of cement (ninety-four pounds [38.04 kilograms]), and an equal volume of dry sand to not more than six gallons [22.71 liters] of clean water. Where large volumes are required to fill annular opening, gravel not larger than one-half inch [12.7 millimeters] in size may be added.

b. **Neat cement grout.** The mixture should consist of one bag of cement (ninety-four pounds [38.04 kilograms]) to not more than six gallons [22.71 liters] of clean water. Additives up to five ~~percent~~ **percent by weight** pounds [11.02 kilograms] per sack of cement to increase fluidity may be used.

c. Heat of hydration. Care must be used when grouting thermoplastic well casing with neat cement grout. Heat caused by hydration during curing of the cement may cause weakening of the well casing. High peak temperatures may be minimized by adding sand or bentonite to the grout mixture to increase the curing time. The amount of bentonite clay added to the cement grout may not exceed five pounds [11.02 kilograms] per sack of cement.

d. Bentonite clay grout. A sodium-base bentonite clay grout may be used to fill the annular space when thermoplastic casing is used. The mixture must consist of not less than two pounds [4.41 kilograms] of bentonite clay per gallon [3.79 liters] of clean water.

The use of drilling fluids as a grouting material is not permitted.

e. **Grouting guides.** ~~Protective casing~~ Casing that is to be grouted in the drill hole or annular opening shall be provided with sufficient guides welded to the casing to permit the unobstructed flow and uniform thickness of grout.

~~d-~~ f. **Grout application.** All grouting shall be performed by adding the mixture, from the bottom of the annular opening upward, in one continuous operation, until the annular opening is filled. Sufficient annular opening shall be provided to permit a minimum of one and one-half inches [3.81 centimeters] of grout around the **protective**

casing, including couplings, if used. Bentonite, ~~aquejil~~, or similar materials may be added to the annular opening in the manner indicated for grouting, to seal any small crevices or fissures, and assure that the space is open prior to final grouting.

9. **Plumbness and alignment.** Every well shall be tested for plumbness and alignment upon completion of construction. The casing shall be sufficiently plumb so as not to interfere with the installation and operation of the pump. (See recommended procedures in the appendix to this chapter.)
10. **Geological data.** Drill cuttings should be obtained at five-foot [1.52-meter] intervals, and at all pronounced changes in formation. The driller shall supply the North Dakota state board of water well contractors with an accurate record of the drill hole diameters and depths, assembled order of size and length of casings and liners, grouting depths, formations penetrated, water levels, location of blast shots, and pumping tests.
11. **Upper terminal of well.** The protective casing or pitless unit for all ground water sources shall project not less than six twelve inches [15-24 30.48 centimeters] above the final ground elevation, and preferably thirteen inches {33-02 centimeters} {mandatory for public water supplies}, above the well cover slab, or pumphouse floor.

Sites not subject to flooding shall have the floor of the pumphouse and the cover of every well dug at least one foot {30-48 centimeters} above original ground surface. Sites subject to flooding shall have the top of the protective casing, pitless unit, the cover of every dug well, and the floor of the pumphouse at least two feet [60.96 centimeters] above the highest known flood elevation and be surrounded by earthfill as required by the reviewing authority.

12. **Capping.** A properly fitted, firmly driven, solid wooden plug shall be the minimum acceptable method of capping a well until pumping equipment is installed. A welded metal plate is preferred. Nonferrous well casing shall be capped using a plug or cap designed for the type of well casing installed. The well must be protected during construction.
13. **Bacteriological quality of water.** Every new, modified, or reconditioned ground water source shall be thoroughly cleaned and disinfected after completion. One or more water samples from the source shall be submitted to a department or other approved laboratory for bacteriological analysis and if found satisfactory shall be approved for placement in service. When it is established that the ground water is subject to

continuous or intermittent contamination, provisions for continuous disinfectant will be required.

14. **Chemical quality of water.** Every new, modified, or reconditioned ground water source should be examined for its chemical characteristics by tests of a representative sample in a department or other approved laboratory. The samples should be collected and tested as soon as practical.
15. **Water level measurement.** Provisions should be made for periodic measurement of the static and pumping water levels in the completed well. The installation shall be made in such manner as to prevent the entrances of foreign material.
16. **Monitoring wells, irrigation wells, geothermal ground water and return wells, and special purpose water wells.** Any water well designed as a monitoring well, irrigation well, geothermal ground water or return well, or for other purposes shall be constructed in accordance with this chapter.

Each well shall be protected at its upper terminal to preclude the entrance of foreign materials.

17. **Abandoned wells.** Any abandoned water wells, including test wells, uncompleted wells, and completed wells shall be sealed by restoring as far as possible the controlling geological conditions which existed before the wells were drilled. **Wherever feasible, the wells should be completely filled with concrete. (See recommended procedures in the appendix to this chapter.)**

Sealing of wells results in:

- a. Elimination of physical hazards.
- b. Prevention of contamination of ground water.
- c. Conserving yield and hydrostatic head of aquifers.
- d. Prevention of intermingling of desirable and undesirable waters.

Wherever feasible the wells should be filled with concrete grout or other approved materials. (Note recommended grouting procedures in the appendix to this chapter.)

At no time shall any sewage or other contaminated or toxic materials be discharged into an abandoned well.

18. **Organic polymers.** The use of biodegradable organic polymers as a drilling fluid additive has resulted in persistent microbiological contamination of ground water supplies.

Organic polymers shall be used only when approved in writing by the department for a specific well construction project.

History: Amended effective January 1, 1984; September 1, 1986.

General Authority: NDCC 43-35-19, 43-35-19.1

Law Implemented: NDCC 43-35-19, 43-35-19.1

33-18-01-07. Pump installation for water wells.

1. **Pumphouse appurtenances.** The installation of necessary appurtenances for public wells shall be as illustrated in pump installation details contained in the diagrams attached to this chapter.
 - a. **Floor drain.** The pumphouse floor shall be watertight and shall slope away from the pump base. The pumphouse floor shall be provided with a floor drain discharging to a sump at least twenty-five feet [7.62 meters] from the well.
 - b. **Vents.** Provisions shall be made for venting the well casing to atmosphere. There shall be no holes in the pump base which might allow wastewater or other material to enter the well. A breather tube shall be installed of sufficient size to permit air to enter and leave the well freely with the changing of water elevation caused by starting and stopping the pump. The breather tube shall terminate in a full one hundred eighty degree bend at least eighteen inches [45.72 centimeters] above the floor, securely screened with sixteen mesh wire screen. If the breather tube or a depth gauge line passes through the base of the pump or through the seal connection into the well, the hole about the tube shall be sealed.
 - c. **Water level measurement.** An access plug for a measuring tape or an air line and drawdown gauge for determining location of the water level shall be installed during the installation of the pump on all public wells. Installation of permanent water level measuring equipment shall be made using corrosion-resistant materials firmly attached, in a vertical position, to the drop pipe or pump column in such a manner as to prevent entrance of foreign materials. The air line shall extend from the top of the well to several feet [meters] below the lowest anticipated water level. The length of the air line shall be accurately measured and the length recorded.
2. **Cutting of well casing.** No casing shall be cut off or cut into below ground level except to install a pitless unit or adapter.
3. **Pitless unit and adapter.**

- a. Pitless unit. Pitless units designed to replace a section of well casing shall be constructed of materials which provide strength and durability equal to the well casing.

Installation shall be by threaded, welded, or compression flange gasketed connection to the cutoff casing. The threaded, welded, or compression flange gasketed connection to the cutoff casing shall be watertight. Pitless units shall form an unbroken extension of the well casing from below the frostline to aboveground level as specified for upper well terminals. The top of the pitless unit shall be capped with a cover having a downward flange which will overlap the edge of the unit. The cover shall be securely fastened to the unit and shall be sufficiently snug to the unit to be verminproof or watertight if required. The cover shall provide for watertight entrance of electrical cables, vent piping, air line, and a tap for wetted tape depth to water level measurements. Pitless adapters for attachment to the exterior of a well casing shall be installed only when approved in writing by the department. must meet the standards of the national sanitation foundation or the water systems council and must:

- (1) Be factory fabricated from point of connection with the well casing to the unit cap or cover. The materials used must be durable, at least equal in quality to the well casing, to prevent excessive corrosion.
- (2) Form an unbroken extension of the well casing from the point of discharge to a point above ground level as specified for upper well terminals.
- (3) Have an inside diameter equal to or greater than the inside diameter of the well casing to facilitate work and repair on the well, pump, or well screen. Any deviation from this paragraph must be approved in writing by the department.
- (4) Conduct water from a well casing without exposing the well to contamination through openings in the casing.
- (5) Have access to the casing for disinfection of the well.
- (6) Be capped with a cover having a downward flange which will overlap the edge of the unit. The cover must be securely fastened to the unit and must be

sufficiently snug to the unit to be verminproof or watertight if required.

The cover must provide for watertight entrance of electrical cables, vent piping, and an air line or a tap for wetted tape measurements of depth to water level of a well.

(7) Be installed by threaded, welded, or compression flange gasketed connection to the cutoff casing. The threaded, welded, or compression flange gasketed connection to the cutoff casing must be watertight. If the connection to the casing is to be a field weld, the factory-assembled unit must be designed specifically for field welding.

(8) Have all field connections between the pitless unit and the water service pipe threaded, flanged, or mechanical joint.

b. Pitless adapter. Pitless adapters for attachment to the exterior of a well casing must be installed only when approved in writing by the department. Pitless adapters must meet the standards of the national sanitation foundation or the water systems council.

(1) Pitless adapters must be constructed and installed so as to prevent the entrance of contaminants into the well or water supply through openings in the well casing.

(2) The pitless adapter must provide adequate clearance within the well to permit insertion and withdrawal of the pump and system components through the upper terminal of the well casing.

(3) The pitless adapter must be connected to the well casing with clamps-and-gasket or by welding and must be watertight. To assure a watertight connection between the pitless adapter and the well casing, care must be used in cutting the hole in the well casing, preferably with a hole-cutting saw. All burs from the cutting process must be removed. Both the outside and the inside surfaces of well casing surrounding the hole must be smooth.

(4) A pitless cap or cover must enclose the upper terminal of the well casing. The cap, entrance of electrical cables, vent piping, air lines, etc., must be as specified for pitless units.

(5) All field connections between the pitless adapter and the water service pipe must be threaded, flanged, or mechanical joint.

(6) All other aspects of pitless adapter requirements must be as specified for pitless units.

c. Freezing. Water service piping must be installed below recorded frost penetration. A minimum depth of seven feet [2.28 meters] below grade is recommended to prevent freezing.

4. **Over-the-well pumps.** Power-driven pumps located over a well shall be installed on a concrete base of sufficient height to permit the outside casing to extend one inch [2.54 centimeters] above the concrete base. On all public water wells the annular opening between the drill hole and casing shall be filled with cement grout before the pump base and pumphouse floor are constructed. If the well is of the gravel wall type, the outer casing shall extend at least twelve inches [30.48 centimeters] above the pumphouse floor with suitable provisions made for adding gravel. The inner casing shall extend one inch [2.54 centimeters] above the pump base. Note diagrams No. 1 and No. 2, pump installation details, in the diagrams attached to this chapter.

A sanitary well seal shall be installed at the top of the well casings to prevent the entrance of contaminated water or objectional material.

5. **Pump column.** A separate pump column, suction or discharge pipe shall be installed inside the well casing in all instances, whether the well is to be pumped by suction, airlift, or deep well pump.

6. **Submersible pumps.** The discharge line shall leave the well at the top of the casing. The opening between the discharge line and casing or pipe sleeve shall be sealed watertight with an expanding rubber seal or equivalent device. When an underground discharge is desired, a properly installed pitless unit or, when approved by the department, a pitless adapter shall be used.

The electrical cable shall be firmly attached to the pump riser at intervals of twenty feet [6.10 meters] or less.

When a check valve is not part of the pump, a check valve shall be installed on the pump discharge line within the well.

A check valve shall be installed in the discharge line above the pump in the well or discharge line.
A check valve on the pump discharge line is not required on nonpressurized wells for livestock use that would be damaged

by freezing, when an airgap or other cross-connection control protection is provided.

7. **Offset pumps.** Pumps offset from public wells shall be located in an aboveground pumphouse or other building. All portions of suction lines buried below the ground surface between the well and the pump shall be enclosed in a protective pipe of standard thickness and be sealed watertight at both ends.

This requirement shall be considered satisfied if the suction line lies within a pressure discharge line.

Offset pumps for private wells may be located in a basement provided that the pumps and all suction pipes are elevated at least twelve inches [30.48 centimeters] above the floor.

8. **Hand pumps.** Hand pumps shall be of the force type equipped with a packing gland around the pump rod, a delivery spout which is closed and downward directed, and a one-piece bell type base which is part of the pump stand or is attached to the pump column in a watertight manner.

The bell base of the pump shall be bolted with a gasket to a flange which is securely attached to the casing or pipe sleeve.

9. Pump controls.

- a. Public water wells. Pump controls for public water wells must be installed in accordance with the manufacturer's recommendations as shown on approved plans and specifications.
- b. Private water wells. Pump controls for private water wells should be installed in accordance with manufacturer's recommendations and must include:
 - (1) A pressure-activated pump switch.
 - (2) A thermal overload switch.
 - (3) A flow control orifice or a low water level cutoff switch on all pumps having an output in excess of the well capacity.
 - (4) A pressure relief valve on positive displacement pumps.
 - (5) The installation of necessary appurtenances for private water wells should be as illustrated in diagram No. 4 - pitless unit and appurtenances for private wells.

History: Amended effective January 1, 1984; September 1, 1986.

General Authority: NDCC 43-35-19, 43-35-19.1

Law Implemented: NDCC 43-35-19, 43-35-19.1

33-18-01-08. Storage tanks.

1. Public water systems. Storage equipment for public water systems must be as shown on approved plans and specifications.
2. Private water systems. Storage equipment must be as follows:
 - a. All tanks must be certified under water system council standards for size and pressure.
 - b. Hydropneumatic tanks must have a working pressure rating in excess of the maximum system pressure but not less than seventy-five pounds per square inch [34.02 kilograms per 6.45 square centimeters].
 - c. All tanks must be coated or made of materials resistant to corrosion.
 - d. All tanks must be constructed of materials or coatings which are nontoxic.
 - e. All tanks must be provided with a means of draining.
 - f. Atmospheric storage tanks must be provided with a cover to prevent the entrance of unauthorized persons, dirt, or vermin. The cover must be vented with a return bend vent pipe having an area not less than the area of the downfeed riser pipe and the vent must be screened with corrosion-resistant screen having not less than fourteen and not more than twenty openings per linear inch [2.54 centimeters].

History: Effective September 1, 1986.

General Authority: NDCC 43-35-19, 43-35-19.1

Law Implemented: NDCC 43-35-19, 43-35-19.1

33-18-01-09. Materials for water distribution.

1. Water service pipe.
 - a. Public water systems. Water service pipe from the well to the point of entrance to a pumphouse or building must be as shown on approved plans and specifications.
 - b. Private water systems. Water service pipe from the well to point of entrance to a pumphouse or building must be made of copper, galvanized steel, or approved plastic.

Approved plastic (polyvinyl chloride, polyethylene, or polybutylene) must have a minimum pressure rating of one hundred sixty pounds per square inch at seventy-three degrees Fahrenheit [11.25 kilograms per square centimeter at 22.8 degrees Celsius]. Copper tube when used underground may not be less than type L. All threaded ferrous pipe and fittings must be galvanized or cement lined and, when used underground in corrosive soil or filled ground, must be coal tar enamel-coated and threaded joints must be coated and wrapped when installed.

All piping must comply with applicable standards for such piping. Polyvinyl chloride, polyethylene, and polybutylene pipe shall carry the seal of the national sanitation foundation.

Permeation through polyethylene and polybutylene pipes by organic contaminants (including petroleum byproducts) can occur resulting in contamination of water supplies. Where there is known contamination of soils by organics or a high probability that contamination of soils by organics may occur, it is recommended that polyethylene and polybutylene pipe not be used to construct water supply lines.

2. Fittings. The materials of which water supply system pipe fittings are made must be compatible with the type of piping materials used in the water supply system.
3. Material strength.
 - a. All materials used for water piping must be suitable for use with the maximum temperature, pressure, and velocity that may be encountered in the installation, including temporary increases and surges.
 - b. When the standards for the piping material used for hot and cold water distribution limit the working pressure or temperature to values lower than usually encountered, the relief valve may be set no higher than the limits of the standard.

History: Effective September 1, 1986.

General Authority: NDCC 43-35-19, 43-35-19.1

Law Implemented: NDCC 43-35-19, 43-35-19.1

33-18-01-10. Cross-connection control - Backflow protection. All wells discharging to sources of contamination such as livestock watering tanks must be provided with an approved backflow prevention device or an airgap to prevent the backflow or siphonage of contaminants into the well. The airgap should provide a minimum vertical distance between the

potable water pipe outlet and the water surface of not less than twice the diameter of the outlet pipe. Greater distances are preferable.

Overflow lines from stock watering tanks or other sources of contamination may not discharge to the well.

Please consult the North Dakota state plumbing code for details.

History: Effective September 1, 1986.

General Authority: NDCC 43-35-19, 43-35-19.1

Law Implemented: NDCC 43-35-19, 43-35-19.1

