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APPENDIX A
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

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

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

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

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

   c. The dimensions of the room or rooms concerned.

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

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

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

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

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

History: Amended effective June 1, 1992.

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

1. **Space requirements.**

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

   b. The operator's booth may be any geometric configuration with no dimension of less than two feet [0.61 meters].

   c. The space shall be allotted excluding any encumbrance by the console, such as overhang, cables, or other similar encroachments.

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

2. **Structural requirements.**

   a. The booth walls shall be permanently fixed barriers of at least seven feet [2.13 meters] high.

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

   c. Shielding must be provided to meet the requirements of chapter 33-10-04.1 of these rules.

3. **X-ray control placement.**

   a. The X-ray control for the system shall be fixed within the booth and:

      (1) Shall be at least forty inches [1.02 meters] from any open edge of the booth wall which is nearest to the examining table.

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

4. **Viewing system requirements.**

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

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

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door, which allows access to the room, cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

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

(1) The viewing area must be at least one square foot [0.0929 square meter].

(2) The design of the booth must be such that the operator's expected position when viewing the patient and operating the X-ray system is at least eighteen inches [0.457 meter] from the edge of the booth.

(3) The material constituting the window must have the same lead equivalence as that required in the booth's wall in which it is mounted.

c. When the viewing system is by mirrors, the mirrors must be so located as to accomplish the general requirements of subdivision a.

d. When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements in subdivision a; and

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

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

APPENDIX C
STRUCTURAL SHIELDING REQUIREMENTS

1. General requirements.

   a. Each installation must be provided with such primary or secondary barriers as are necessary to assure compliance with section 33-10-04.1-06 and section 33-10-04.1-07. This requirement must be deemed to be met if the thicknesses of such barriers are equivalent to those as computed in accordance with appendices B, C, and D of the National Council on Radiation Protection and Measurements Report No. 49, "Medical X-ray and Gamma-Ray Protection For Energies Up to 10 MeV," modified to meet current dose limits.

   b. Lead barriers must be mounted in such manner that they will not sag or cold-flow because of their own weight and shall be protected against mechanical damage.

   c. Joints between different kinds of protective materials must be designed so that the overall protection of the barrier is not impaired.

   d. Joints at the floor and ceiling must be so designed that the overall protection is not impaired.

   e. Windows, window frames, doors, and door frames must have the same lead equivalent as that required of the adjacent wall.

   f. Holes in protective barriers must be covered so that overall attenuation is not impaired.

2. Fluoroscopic X-ray systems. Ordinarily only secondary barriers are necessary except combined fluoroscopic-radiographic installations.

3. Radiographic systems other than fluoroscopic, dental intraoral, or veterinarian systems:

   a. All wall, floor, and ceiling areas exposed to the useful beam must have primary barriers. Primary barriers in walls must extend to a minimum height of eighty-four inches [2.13 meters] above the floor.

   b. Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier requirements are lower than the secondary requirements.

   c. The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a

shield which will intercept the useful beam and any radiation which has been scattered only once.

d. A window of lead equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure.

e. For mobile and portable X-ray systems which are used for greater than one week in one location (one room or suite), the requirements of this appendix shall apply.

4. Intraoral dental radiographic systems.

a. Dental rooms containing X-ray machines shall be provided with primary barriers at all areas struck by the useful beam. Consideration shall be given to the attenuation provided by the patient.

b. When dental X-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas.

Note: In many cases, structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.

5. Therapeutic X-ray installations. The structural shielding requirements shall be deemed to be met if the barriers have been designed and constructed in accordance with the National Council on Radiation Protection and Measurements Report No. 49, "Medical X-ray and Gamma-Ray Protection for Energies Up To 10 MeV", modified to meet current dose limits.

6. Veterinary medicine radiographic installations.

a. All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four inches [2.13 meters] above the floor.

b. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier requirements are lower than the secondary requirements.

APPENDIX D
X-RAY FILM DEVELOPING

Time Temperature Chart

Thermometer Readings (Degrees)			Minimum Developing Times (Minutes)
C		F	
27	-	80	2
		79	2
		78	2 1/2
		77	2 1/2
24	-	76	3
		75	3
		74	3 1/2
		73	3 1/2
22	-	72	4
		71	4
		70	4 1/2
		69	4 1/2
20	-	68	5
		67	5 1/2
		66	5 1/2
		65	6
18	-	64	6 1/2
		63	7
		62	8
		61	8 1/2
16	-	60	9 1/2

Processing of Film

1. Manual processing of film.

   a. Where film is developed manually, processing tanks should be made of mechanically rigid, corrosion resistant material and the temperature of solutions in the tanks shall be maintained within the range of sixteen degrees Celsius to twenty-seven degrees Celsius [60-80 degrees Fahrenheit]. Film shall be developed in accordance

with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the above time-temperature chart.

b. Devices shall be available which will give all of the following:

(1) The actual temperature of the developer.

(2) An audible or visible signal, after a preset time (in minutes of duration).

2. Automatic processors and other closed processing systems.

a. Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

b. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

c. Preventive maintenance shall be performed on the unit, except for extended periods of nonuse, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer a maintenance schedule shall be established which will preserve good film quality.

d. After a full cleansing of the processor a film shall be exposed to a density of approximately one, with one-half of the film protected exposure. It will be developed and then kept near the unit and daily at least one test film (exposed under techniques identical with those used for the original test film) shall be compared with the original test film to evaluate the adequacy of the unit's developing capability and base fog level.

3. Processing deviations from the requirements of appendix D shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

4. Other requirements:

a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1

(0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

c. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

APPENDIX E
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

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

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

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

3. A detailed description of the X-ray examinations proposed in the screening program.

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

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

6. An evaluation by a qualified expert on the X-ray systems to be used in the screening program. The evaluation by the qualified expert shall show that such systems do satisfy all requirements of this article. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the diagnostic X-ray quality control program.

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

9. The qualifications of each individual who will be operating the X-ray systems.

10. The qualifications of the individual who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiographs.

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

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

14. An indication of the frequency of screening and the duration of the entire screening program.

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; May 1, 1998.

APPENDIX F
GENERAL TRAINING REQUIREMENTS FOR ALL X-RAY OPERATORS

The department may use interview, observation and/or testing to determine compliance. The following are areas in which an individual shall have expertise for the competent operation of X-ray equipment:

1. Fundamentals of radiation safety.
    a. Characteristics of X-radiation.
    b. Units of radiation dose (mrem).
    c. Hazards of exposure to radiation.
    d. Levels of radiation from sources of radiation.
    e. Methods of controlling radiation dose.
        (1) Working time.
        (2) Working distance.
        (3) Shielding.
        (4) Collimation.
        (5) Filtration.
        (6) Gonad shielding and other patient protection devices.
        (7) Restriction of X-ray beam to the image receptor.
        (8) Grid utilization.
        (9) Utilization of mechanical immobilization device.
2. Familiarization with equipment.
    a. Identification of controls.
    b. Function of each control.
    c. How to use a technique chart.
3. Film processing.
    a. Film speed as related to patient exposure.

b. Film processing parameters.

c. Quality assurance program.

4. Emergency procedures.

a. Termination of exposure in event of automatic timing device failure.

5. Proper use of personnel dosimetry.

a. Location of dosimeter.

b. Interpretation of personnel monitoring reports.

6. Anatomy and positioning.

a. Relevant human anatomy.

b. Relevant human physiology.

c. Radiographic positioning.

7. The requirements of pertinent federal and state rules.

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

APPENDIX G

The following are individuals that qualify for training exemptions, approved Allied Health professions which qualify for cross-training into diagnostic X-ray as a limited diagnostic operator and individuals who may order diagnostic X-rays to be taken by a limited diagnostic operator outside the scope of procedures in appendix I:

1. Individuals exempt from minimum training requirements in subparagraph b of paragraph 2 of subdivision a of subsection 1 of section 33-10-06-03.

   a. Medical doctors.

   b. Chiropractors.

   c. Doctors of osteopathy.

   d. Podiatrists.

2. Prerequisite qualification: Individuals who qualify for cross-training as a limited diagnostic operator.

   a. Nurse practitioner, registered nurse, licensed practical nurse.

   b. Emergency medical technician paramedic.

   c. Physical therapist, physical therapy assistant.

   d. Occupational therapist, occupational therapy assistant.

   e. Medical technologist, medical lab technician, clinical lab technician.

   f. Physician assistant.

   g. Orthopedic physician assistant.

3. Individuals who may order emergency X-ray examinations outside the scope of procedures in appendix I to be taken by limited diagnostic operators:

   a. Medical doctor.

   b. Doctor of osteopathy.

   c. Physician assistant.

   d. Nurse practitioner.

e. Chiropractor.

APPENDIX H
Limited Diagnostic Operator Training Requirements

Students must meet the prerequisite requirements of item 1 of subparagraph b of paragraph 2 of subdivision a of subsection 1 of section 33-10-06-03 and complete the training requirements of this appendix.

Training requirements have been divided into two sections, didactic instruction and clinical experience/supervision. Upon completion of didactic training, the individual must complete the clinical experience requirements of either subdivision a or b of subsection 2 and demonstrate competence for examinations listed in appendix I. Records must be maintained to demonstrate compliance with these requirements.

1. Didactic instruction section: Individuals shall complete a minimum of eighty hours of didactic training at a single course providing the minimum hours of instruction in the subjects below. Correspondence coursework cannot exceed twenty percent of the eighty-hour course (sixteen hours maximum). The course content should approximate the outline below. The eighty-hour course is subject to department approval. Individuals must also complete the three-hour self study course designed by the state health department. An examination is required to demonstrate successful completion of a course.

a. Basic X-ray Physics — 12 hrs.
   - general description of production of X-rays
   - function of filtration and effects it has on X-ray beam
   - collimation
   - types and function of beam limiting devices
   - design, features and function of X-ray tube

b. Radiobiology — 1 hr.
   - effects of ionizing radiation to the human body
   - factors that cause somatic and genetic damage

c. Radiation Protection — 6 hrs.
   - ALARA concept
   - shielding materials
   - radiation quantity and units of measurement
   - basic interactions of X-ray with matter
   - primary and secondary scatter
   - importance of time, distance, shielding
   - maximum permissible dose-occupational/public

- latency period
- patient protection

d. Principles of Exposure 15 hrs.
- factors that control and influence radiographic quality
- properties of X-rays
- size distortion caused by geometric parameters
- parameters which cause shape distortion
- technique factor selection
- 15% rule, mAs and kVp relationship
- grid-types, ratios, and how they affect image quality
- intensifying screens
- X-ray film
- artifacts
- inverse square law

e. Darkroom Procedure and Processing 4 hrs.
- film storage and handling
- film processing and troubleshooting
- design, features and function of a processor
- silver recovery
- quality assurance/quality control

f. Anatomy and Positioning

1. Chest 4 hrs.
2. Abdomen 4 hrs.
3. Extremity 8 hrs.
4. Spine 8 hrs.
5. Skull 8 hrs.

2. Clinical experience/supervision section. Individuals must complete either a or b below. If the individual is unable to demonstrate clinical competence in a procedure due to a lack of opportunity, the student shall complete the three prerequisite examinations required by appendix J using simulation for subdivisions a through k of subsection 1 of appendix J. Final demonstration of competence in subdivisions a through s of subsection 1 of appendix J should be completed as soon as there is a patient requiring the procedure. No individual may perform

an unsupervised procedure for which they have not successfully completed the final demonstration of competence.

a. The individual must complete three months of clinical training during which time they may perform X-ray examinations only under direct supervision.

(1) Direct supervision and evaluation of competence shall be performed by a general diagnostic operator or a limited diagnostic operator with two years' experience.

(2) The individual shall utilize proper procedure as indicated in appendix J.

(3) The individual shall be evaluated on procedure, performance and competency on forms provided by the department for each of the examinations listed in appendix I; or

b. Individuals must complete at least one hundred twenty hours of clinical training at a facility where there is routinely fifty or more limited diagnostic X-ray examinations performed per week. During this time they may perform X-ray examinations only under direct supervision. After completing the one hundred twenty hours of training, the individual must complete an additional three-month probationary training period as outlined in number 4 of this part.

(1) Direct supervision and evaluation of competence shall be performed by a general diagnostic operator or a limited diagnostic operator with a two years experience.

(2) The individual shall utilize proper procedure as indicated in appendix J.

(3) The individual shall be evaluated on procedure performance and competency on forms provided by the department for each of the examinations listed in appendix I.

(4) Upon completion of one hundred twenty clinical hours and demonstration of competence in accordance with appendix J for limited diagnostic operator examinations:

(a) Individuals must complete a three-month probationary training period during which time they may independently perform limited diagnostic operator examinations for the procedures which they have successfully demonstrated competence.

(b) During the three-month probationary training, a general diagnostic operator, or a limited diagnostic operator with

two years' experience, or a radiologist must evaluate all films and conduct at least six hours of direct supervision on a weekly basis and give feedback on any needed improvements.

[1] All films, including repeat and waste films, must be kept for evaluation.

[2] Evaluation must be done on forms supplied by the department.

APPENDIX I

Specific examinations that are allowed in the scope of practice for limited diagnostic operators.

Chest:	PA, lateral, decubitus
Ribs:	AP, PA, obliques
Abdomen:	KUB, upright abdomen
Hand & fingers:	PA, lateral, oblique
Wrist:	PA, lateral, oblique
Forearm:	AP, lateral
Elbow:	AP, lateral
Humerus:	AP, lateral
Shoulder:	AP, internal & external rotation
Clavicle:	AP, AP axial
Pelvis:	AP
Hips:	AP, Frog leg lateral, cross-table lateral
Femur:	AP, lateral
Knee:	AP, lateral
Tibia-Fibula:	AP, lateral
Ankle:	AP, lateral, obliques
Foot & toes:	AP, lateral, obliques
Sinuses:	Water's, lateral
Skull:	AP/PA, lateral
Facial bones:	PA, lateral
C-spine:	AP, lateral, odontoid, (not trauma), swimmer's (not trauma)
T-spine:	AP, lateral, swimmer's (not trauma)
L-spine:	AP, lateral, L5-S1 lateral

Any situation deemed an emergency and requiring a limited diagnostic operator to conduct procedures not specifically listed above, requires a written order from an individual listed in part 3 of appendix G and direct supervision from the individual ordering the examination in accordance with item 1 of subparagraph c of paragraph 2 of subdivision a of subsection 1 of section 33-10-06-03.

APPENDIX J
X-ray Procedure and Image Competency Criteria

An individual must perform at least three examinations prior to requesting a final competency evaluation for each of the limited scope examinations listed in appendix I. The three preevaluation examinations should be on actual patients but may be simulated if there is an insufficient number of patients requiring the procedure during the students clinical competency training period. The evaluations shall be documented on forms provided by the department. The final competency evaluation must be on an actual patient. To pass a final competency evaluation, the individual must receive an acceptable rating in each of the criteria listed below.

1. At a minimum, the following criteria must be evaluated during a procedure and image competency evaluation involving an actual patient. Simulated procedures need to evaluate only subdivisions a through k below:

   a. Select appropriate film size.

   b. Select appropriate technique.

   c. Use correct source-to-image distance.

   d. Establish proper direction of central ray.

   e. Execute proper patient position.

   f. Collimate if appropriate.

   g. Provide gonadal shielding if appropriate.

   h. Use correct film markers.

   i. Give proper patient instruction.

   j. Place patient information correctly on the film.

   k. Complete examination in an acceptable time limit.

   l. All anatomical parts included on the film.

   m. Correct positioning of anatomical parts.

   n. Appropriate contrast.

   o. Adequate density.

   p. Correct use of right and left markers.

q. Proper accessory markers as needed.

r. No visible motion.

s. Patient information correct and clearly visible.

2. If the individual is unable to demonstrate clinical competence while completing the requirements for clinical supervision in either subdivision a or b of subsection 2 of appendix H due to a lack of opportunities to conduct certain procedures, the student shall complete the three prerequisite examinations using simulation for subdivisions a through k of subsection 1. Final demonstration of competence in subdivisions a through s of subsection 1 should be completed as soon as there is a patient requiring the procedure. No individual may perform an unsupervised procedure for which they have not successfully completed the final demonstration of competence.

APPENDIX K
Training exemption and demonstration of competence for individuals with greater than two years experience

After six months from the effective date of this regulation, limited diagnostic operators meeting the requirements of this regulation in accordance with this appendix may only perform procedures in the examinations in which they have successfully demonstrated competence. Prior examinations are not necessary for demonstrating competence in accordance with this appendix.

1. Training exemption.

   Individuals who have completed two years of experience prior to the effective date of this regulation and have not attended an eighty-hour didactic training program as identified in item 2 of subparagraph b of paragraph 2 of subdivision a of subsection 1 of section 33-10-06-03 are exempt from completing the eighty-hour didactic training if they can demonstrate they have completed at least eighty hours of relevant X-ray training regardless of the length of the individual training session prior to the effective date of this regulation; and

2. Demonstrate competence in accordance with this appendix as follows:

   a. Competence shall be determined by a general diagnostic operator on forms provided by the department; and

   b. Competence shall include successful demonstration of items 1 a through s of appendix J for all procedures listed in appendix I.

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

[Repealed effective March 1, 2003]

CHAPTER 33-10-07.1
MEDICAL USE OF RADIOACTIVE MATERIAL

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33-10-07.1-121	Report of a Leaking Source

33-10-07.1-01. Purpose and scope. This chapter contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this chapter are in addition to, and not in substitution for, others in article 33-10. The requirements and provisions of chapters 33-10-01, 33-10-03,

33-10-04.1, 33-10-10, 33-10-11, and 33-10-13 apply to applicants and licensees subject to this chapter unless specifically exempted.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-02. Definitions.

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

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

3. "Authorized medical physicist" means an individual who:

   a. Meets the requirements in subsection 1 of section 33-10-07.1-21 (training for an authorized medical physicist) and section 33-10-07.1-24 (recentness of training); or

   b. Is identified as an authorized medical physicist or teletherapy physicist on:

      (1) A specific medical use license issued by the United States nuclear regulatory commission or an agreement state or a licensing state;

      (2) A medical use permit issued by a United States nuclear regulatory commission master material licensee;

      (3) A permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope medical use licensee; or

      (4) A permit issued by a United States nuclear regulatory commission master material license broad scope medical use permittee.

4. "Authorized nuclear pharmacist" means a pharmacist who:

   a. Meets the requirements in subsection 1 of section 33-10-07.1-22 (training for an authorized nuclear pharmacist) and section 33-10-07.1-24 (recentness of training);

   b. Is identified as an authorized nuclear pharmacist on:

(1) A specific license issued by the United States nuclear regulatory commission or an agreement state or a licensing state that authorizes medical use or the practice of nuclear pharmacy;

(2) A permit issued by a United States nuclear regulatory commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(3) A permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(4) A permit issued by a United States nuclear regulatory commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with subparagraph d of paragraph 2 of subdivision i of subsection 5 of section 33-10-03-05 or 10 CFR 32.72(b)(4).

5. Authorized user means a physician, dentist, or podiatrist who:

a. Meets the requirements in section 33-10-07.1-24 (recentness of training) and subsection 1 of section 33-10-07.1-36 (training for uptake, dilution, and excretion studies), subsection 1 of section 33-10-07.1-40 (training for imaging and localization studies), subsection 1 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), subsection 1 of section 33-10-07.1-45 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries]), subsection 1 of section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]), subsection 1 of section 33-10-07.1-55 (training for use of manual brachytherapy sources), subsection 1 of section 33-10-07.1-58 (training for use of sealed sources for diagnosis), or subsection 1 of section 33-10-07.1-75 (training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units); or

b. Is identified as an authorized user on:

(1) A United States nuclear regulatory commission or agreement state or licensing state license that authorizes the medical use of radioactive material;

(2) A permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the medical use of radioactive material;

(3) A permit issued by a United States nuclear regulatory commission or agreement state or licensing state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(4) A permit issued by a United States nuclear regulatory commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

6. "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

7. "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

8. "Client's address" means the area of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with section 33-10-07.1-33 (provision of mobile medical service).

9. "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

10. "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

11. "High dose-rate remote afterloader", as used in this chapter, means a brachytherapy device that remotely delivers a dose rate in excess of twelve gray [1200 rads] per hour at the point or surface where the dose is prescribed.

12. "Low dose-rate remote afterloader", as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of less than or equal to two gray [200 rads] per hour at the point or surface where the dose is prescribed.

13. "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

14. "Manual brachytherapy", as used in this chapter, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

15. "Medical event" means an event that meets the criteria in subsection 1 of section 33-10-07.1-119 (report and notification of a medical event).

16. "Medical institution" means an organization in which more than one medical discipline is practiced.

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

18. "Medium dose-rate remote afterloader", as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of greater than two gray [200 rads], but less than twelve gray [1200 rads] per hour at the point or surface where the dose is prescribed.

19. "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

20. "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

21. "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

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

23. "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

24. "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

25. "Preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

26. "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

    a. In a written directive; or

    b. In accordance with the directions of the authorized user for procedures performed pursuant to section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) and section 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required).

27. "Prescribed dose" means:

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

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

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

    d. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

28. "Pulsed dose-rate remote afterloader", as used in this chapter, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

    a. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

    b. Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

29. "Radiation safety officer" means an individual who:

a. Meets the requirements in subsection 1 of section 33-10-07.1-20 (training for radiation safety officer) and section 33-10-07.1-24 (recentness of training); or

b. Is identified as a radiation safety officer on:

(1) A specific medical use license issued by the United States nuclear regulatory commission or an agreement state or a licensing state; or

(2) A medical use permit issued by a United States nuclear regulatory commission master material licensee.

30. "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by the United States nuclear regulatory commission and the agreement states and the licensing states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

31. "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

32. "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

33. "Teletherapy", as used in this chapter, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

34. "Temporary jobsite" means a location where mobile medical services are conducted other than those locations of use authorized on the license.

35. "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

36. "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

37. "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

38. "Type of use" means use of radioactive material under section 33-10-07.1-35 (use of unsealed radioactive material for uptake,

dilution, and excretion studies for which a written directive is not required), 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required), 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required), 33-10-07.1-47 (use of sources for manual brachytherapy), 33-10-07.1-57 (use of sealed sources for diagnosis), 33-10-07.1-59 (use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit), or 33-10-07.1-89 (other medical uses of radioactive material or radiation from radioactive material).

39. "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

40. "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in section 33-10-07.1-17 (written directives).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-03. Maintenance of records. Each record required by this chapter must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-04. Provisions for the protection of human research subjects.

1. A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

2. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented the federal policy for the protection of human subjects, the licensee shall, before conducting research:

   a. Obtain review and approval of the research from an "institutional review board", as defined and described in the federal policy for the protection of human subjects; and

   b. Obtain "informed consent", as defined and described in the federal policy for the protection of human subjects, from the human research subject.

3. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the federal policy for the protection of human subjects, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license from the department. The amendment request must include a written commitment that the licensee will, before conducting research:

   a. Obtain review and approval of the research from an "institutional review board", as defined and described in the federal policy for the protection of human subjects; and

   b. Obtain "informed consent", as defined and described in the federal policy for the protection of human subjects, from the human research subject.

4. Nothing in this section relieves licensees from complying with the other requirements in this chapter.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-05. Food and drug administration, other federal, and state requirements. Nothing in this chapter relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs or devices.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-06. Implementation.

1. A licensee shall implement the provisions in this chapter on or before September 1, 2003, with the exception of the requirements listed in subsection 2.

2. A licensee shall implement the training requirements in subsection 1 of section 33-10-07.1-20 (training for radiation safety officer), subsection 1 of section 33-10-07.1-21 (training for an authorized medical physicist), subsection 1 of section 33-10-07.1-22 (training for an authorized nuclear pharmacist), section 33-10-07.1-24 (recentness of training), subsection 1 of section 33-10-07.1-36 (training for uptake, dilution, and excretion studies), subsection 1 of section 33-10-07.1-40 (training for imaging and localization studies), subsection 1 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), subsection 1 of section 33-10-07.1-45 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries]), subsection 1 of section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]), subsection 1 of section 33-10-07.1-55 (training for use of manual brachytherapy sources), subsection 1 of section 33-10-07.1-58 (training for use of sealed sources for diagnosis), and subsection 1 of section 33-10-07.1-75 (training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units) on or before October 25, 2004.

3. Prior to October 24, 2004, a licensee shall satisfy the training requirements of this chapter for a radiation safety officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

   a. The appropriate training requirements in sections 33-10-07.1-76 through 33-10-07.1-88; or

   b. The appropriate training requirements in sections 33-10-07.1-14 through 33-10-07.1-24 or sections 33-10-07.1-35 through 33-10-07.1-75.

4. If a license condition exempted a licensee from a provision of this chapter on September 1, 2003, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of this chapter.

5. When a requirement in this chapter differs from the requirement in an existing license condition, the requirement in this chapter shall govern.

6. A licensee shall continue to comply with any license condition that requires it to implement procedures required by sections 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader

units), and 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units) until there is a license amendment or renewal that modifies the license condition.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-07. License required.

1. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the United States nuclear regulatory commission or an agreement state or a licensing state, or as allowed in subsection 2.

2. A specific license is not needed for an individual who:

   a. Receives, possesses, uses, or transfers radioactive material in accordance with article 33-10 (radiological health rules) under the supervision of an authorized user as provided in section 33-10-07.1-16 (supervision), unless prohibited by license condition; or

   b. Prepares unsealed radioactive material for medical use in accordance with article 33-10 (radiological health rules) under the supervision of an authorized nuclear pharmacist or authorized user as provided in section 33-10-07.1-16 (supervision), unless prohibited by license condition.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-08. Application for license, amendment, or renewal.

1. An application must be signed by the applicant's or licensee's management.

2. An application for a license for medical use of radioactive material as described in sections 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required), 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required), 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required), 33-10-07.1-47 (use of sources for manual brachytherapy), 33-10-07.1-57 (use of sealed sources for diagnosis), 33-10-07.1-59 (use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery

unit), and 33-10-07.1-89 (other medical uses of radioactive material or radiation from radioactive material) must be made by:

a. Filing an application for medical use of radioactive material that includes the facility diagram, equipment, and training and experience qualifications of each radiation safety officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist; and

b. Submitting procedures required by sections 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), and 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units), as applicable.

3. A request for a license amendment or renewal must be made by:

a. Submitting either an application for medical use of radioactive material or a letter requesting the amendment or renewal; and

b. Submitting procedures required by sections 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), and 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units), as applicable.

4. In addition to the requirements in subsections 2 and 3, an application for a license or amendment for medical use of radioactive material as described in section 33-10-07.1-89 (other medical uses of radioactive material or radiation from radioactive material) must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in sections 33-10-07.1-01 through 33-10-07.1-34.

a. The applicant shall also provide specific information on:

(1) Radiation safety precautions and instructions;

(2) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(3) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

b. The applicant or licensee shall also provide any other information requested by the department in its review of the application.

5. An applicant that satisfies the requirements specified in subdivision b of subsection 4 (special requirements for specific licenses of broad scope) of section 33-10-03-05 may apply for a type A specific license of broad scope.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-09. License amendments. A licensee shall apply for and must receive a license amendment:

1. Before it receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but that is not authorized on the licensee's current license issued under this chapter;

2. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except:

   a. For an authorized user, an individual who meets the requirements in section 33-10-07.1-24 (recentness of training) and subsection 1 of section 33-10-07.1-36 (training for uptake, dilution, and excretion studies), subsection 1 of section 33-10-07.1-40 (training for imaging and localization studies), subsection 1 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), subsection 1 of section 33-10-07.1-45 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries]), subsection 1 of section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]), subsection 1 of section 33-10-07.1-55 (training for use of manual brachytherapy sources), subsection 1 of section 33-10-07.1-58 (training for use of sealed sources for diagnosis), subsection 1 of section 33-10-07.1-75 (training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units), section 33-10-07.1-77 (training for uptake, dilution, and excretion studies), section 33-10-07.1-78 (training for imaging and localization studies), section 33-10-07.1-79 (training for therapeutic use of unsealed radioactive material), section 33-10-07.1-80 (training for treatment of hyperthyroidism), section 33-10-07.1-81 (training for treatment of thyroid carcinoma), section 33-10-07.1-82 (training for use of brachytherapy sources), section 33-10-07.1-83 (training for

ophthalmic use of strontium-90), section 33-10-07.1-84 (training for use of sealed sources for diagnosis), or section 33-10-07.1-85 (training for use of therapeutic medical devices);

b. For an authorized nuclear pharmacist, an individual who meets the requirements in subsection 1 of section 33-10-07.1-22 (training for an authorized nuclear pharmacist) or section 33-10-07.1-87 (training for an authorized nuclear pharmacist) and section 33-10-07.1-24 (recentness of training);

c. For an authorized medical physicist, an individual who meets the requirements in subsection 1 of section 33-10-07.1-21 (training for an authorized medical physicist) or section 33-10-07.1-86 (training for an authorized medical physicist) and section 33-10-07.1-24 (recentness of training); and

d. An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

(1) On a United States nuclear regulatory commission or agreement state or licensing state license or other equivalent permit or license recognized by the department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) On a permit issued by a United States nuclear regulatory commission or agreement state or licensing state specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(3) On a permit issued by a United States nuclear regulatory commission master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;

3. Before it changes radiation safety officers, except as provided in subsection 3 of section 33-10-07.1-14 (authority and responsibilities for the radiation protection program);

4. Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

5. Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material

is used only in accordance with either section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) or section 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required);

6. Before it changes an address of use identified in the application or on the license; and

7. Before it revises procedures required by sections 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), and 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units), as applicable, if such revision reduces radiation safety.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-10. Notifications.

1. A licensee shall provide the department a copy of the board certification, the United States nuclear regulatory commission or agreement state or licensing state license, the permit issued by a United States nuclear regulatory commission master material licensee, the permit issued by a United States nuclear regulatory commission or agreement state or licensing state licensee of broad scope, or the permit issued by a United States nuclear regulatory commission master material license broad scope permittee for each individual no later than thirty days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under subsection 2 of section 33-10-07.1-09 (license amendments).

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

   a. An authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

   b. The licensee's mailing address changes;

   c. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in

subdivision b of subsection 7 (specific terms and conditions of licenses) of section 33-10-03-05; or

d. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) or section 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required).

3. The licensee shall mail the documents required in this section to the department at the address identified in section 33-10-01-13 (communications).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-11. Exemptions regarding type A specific licenses of broad scope. A licensee possessing a type A specific license of broad scope for medical use, issued under subsection 4 (special requirements for specific licenses of broad scope) of section 33-10-03-05, is exempt from:

1. The provisions of subsection 4 of section 33-10-07.1-08 (application for license, amendment, or renewal) regarding the need to file an amendment to the license for medical use of radioactive material, as described in section 33-10-07.1-89 (other medical uses of radioactive material or radiation from radioactive material);

2. The provisions of subsection 2 of section 33-10-07.1-09 (license amendments);

3. The provisions of subsection 5 of section 33-10-07.1-09 (license amendments) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

4. The provisions of subsection 1 of section 33-10-07.1-10 (notifications);

5. The provisions of subdivision a of subsection 2 of section 33-10-07.1-10 (notifications) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

6. The provisions of subdivision d of subsection 2 of section 33-10-07.1-10 (notifications) regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) or section 33-10-07.1-37

(use of unsealed radioactive material for imaging and localization studies for which a written directive is not required); and

7. The provisions of subsection 1 of section 33-10-07.1-19 (suppliers for sealed sources or devices for medical use).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-12. License issuance.

1. The department shall issue a license for the medical use of radioactive material if:

   a. The applicant has filed an application for medical use of radioactive material in accordance with the instructions in section 33-10-07.1-08 (application for license, amendment, or renewal);

   b. The applicant has paid any applicable fee as provided in chapter 33-10-11 (fees for issuance of license and registration certificates and inspections);

   c. The department finds the applicant equipped and committed to observe the safety standards established by the department in article 33-10 (radiological health rules) for the protection of the public health and safety; and

   d. The applicant meets the requirements of chapter 33-10-03 (licensing of radioactive material).

2. The department shall issue a license for mobile medical service if the applicant:

   a. Meets the requirements in subsection 1; and

   b. Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-13. Specific exemptions. The department may, upon application of any interested person or upon its own initiative, grant exemptions

from the rules in this chapter that it determines are authorized by law, will not endanger life or property or the common defense and security and are otherwise in the public interest.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-14. Authority and responsibilities for the radiation protection program.

1. In addition to the radiation protection program requirements of section 33-10-04.1-05 (radiation protection programs), a licensee's management shall approve in writing:

   a. Requests for a license application, renewal, or amendment before submittal to the department;

   b. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

   c. Radiation protection program changes that do not require a license amendment and are permitted under section 33-10-07.1-15 (radiation protection program changes).

2. A licensee's management shall appoint a radiation safety officer, who agrees in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

3. For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer, under sections 33-10-07.1-20 (training for radiation safety officer) and 33-10-07.1-24 (recentness of training), to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in subsection 7, if the licensee takes the actions required in subsections 2, 5, 7, and 8 and notifies the department in accordance with subsection 2 of section 33-10-07.1-10 (notifications).

4. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with subsection 3, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

5. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

6. Licensees that are authorized for two or more different types of uses of radioactive material under sections 33-10-07.1-41 through 33-10-07.1-56 and sections 33-10-07.1-59 through 33-10-07.1-75, or two or more types of units under sections 33-10-07.1-59 through 33-10-07.1-75, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The radiation safety committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The radiation safety committee may include other members the licensee considers appropriate.

7. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

   a. Identify radiation safety problems;

   b. Initiate, recommend, or provide corrective actions;

   c. Stop unsafe operations; and

   d. Verify implementation of corrective actions.

8. A licensee shall retain a record of actions taken under subsections 1, 2, and 5 in accordance with section 33-10-07.1-90 (records of authority and responsibilities for radiation protection programs).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-15. Radiation protection program changes.

1. A licensee may revise its radiation protection program without department approval if:

   a. The revision does not require a license amendment under section 33-10-07.1-09 (license amendments);

   b. The revision is in compliance with article 33-10 (radiological health rules) and the license;

   c. The revision has been reviewed and approved by the radiation safety officer and licensee management; and

d. The affected individuals are instructed on the revised program before the changes are implemented.

2. A licensee shall retain a record of each change in accordance with section 33-10-07.1-91 (records of radiation protection program changes).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-16. Supervision.

1. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by subdivision a of subsection 2 of section 33-10-07.1-07 (license required), shall:

   a. In addition to the requirements in subsection 2 (instructions to workers) of section 33-10-10-02, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules in article 33-10 (radiological health rules), and license conditions with respect to the use of radioactive material; and

   b. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules in article 33-10 (radiological health rules), and license conditions with respect to the medical use of radioactive material.

2. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by subdivision b of subsection 2 of section 33-10-07.1-07 (license required), shall:

   a. In addition to the requirements in subsection 2 (instructions to workers) of section 33-10-10-02, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

   b. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee,

the rules in article 33-10 (radiological health rules), and license conditions.

3. A licensee that permits supervised activities under subsections 1 and 2 is responsible for the acts and omissions of the supervised individual.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-17. Written directives.

1. A written directive must be dated and signed by an authorized user before the administration of sodium iodide I-131 greater than one thousand one hundred ten kilobecquerels [30 microcuries], any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

   If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty-eight hours of the oral directive.

2. The written directive must contain the patient or human research subject's name and the following information:

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

   b. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

   c. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

   d. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

   e. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

   f. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(1) Before implantation: treatment site, the radionuclide, and dose; and

(2) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

3. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

   If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within forty-eight hours of the oral revision.

4. The licensee shall retain a copy of the written directive in accordance with section 33-10-07.1-92 (records of written directives).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-18. Procedures for administrations requiring a written directive.

1. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

   a. The patient's or human research subject's identity is verified before each administration; and

   b. Each administration is in accordance with the written directive.

2. At a minimum, the procedures required by subsection 1 must address the following items that are applicable to the licensee's use of radioactive material:

   a. Verifying the identity of the patient or human research subject;

   b. Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

c. Checking both manual and computer-generated dose calculations; and

d. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by section 33-10-07.1-59 (use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit).

3. A licensee shall retain a copy of the procedures required under subsection 1 in accordance with section 33-10-07.1-93 (records for procedures for administrations requiring a written directive).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-19. Suppliers for sealed sources or devices for medical use. For medical use, a licensee may only use:

1. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under chapter 33-10-03 (licensing of radioactive material) and subdivision j (manufacture and distribution of sources or devices containing radioactive material for medical use) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state;

2. Sealed sources or devices noncommercially transferred from a licensee under this chapter; or

3. Teletherapy sources manufactured and distributed in accordance with a license issued under chapter 33-10-03 (licensing of radioactive material) or the equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-20. Training for radiation safety officer. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in section 33-10-07.1-14 (authority and responsibilities for the radiation protection program) to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been

recognized by the United States nuclear regulatory commission or an agreement state or a licensing state;

2. a. Has completed a structured educational program consisting of both:

(1) Two hundred hours of didactic training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(e) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a United States nuclear regulatory commission or agreement state or licensing state license or permit issued by a United States nuclear regulatory commission master material licensee that authorizes similar type of use of radioactive material involving the following:

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(c) Securing and controlling radioactive material;

(d) Using administrative controls to avoid mistakes in the administration of radioactive material;

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(f) Using emergency procedures to control radioactive material; and

(g) Disposing of radioactive material; and

b. Has obtained written certification, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the structured educational program requirements in subdivision a of subsection 2 and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or

3. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-21. Training for an authorized medical physicist. Except as provided in section 33-10-07.1-23 (training for an experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized medical physicist to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in sections 33-10-07.1-29 (requirements for possession of sealed sources and brachytherapy sources), 33-10-07.1-53 (decay of strontium-90 sources for ophthalmic treatments), 33-10-07.1-65 (full calibration measurements on teletherapy units), 33-10-07.1-66 (full calibration measurements on remote afterloader units), 33-10-07.1-67 (full calibration measurements on gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units), and 33-10-07.1-72 (radiation surveys), as applicable; and

b. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 and has achieved a level of competency sufficient

to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in section 33-10-07.1-21 (training for an authorized medical physicist) or equivalent United States nuclear regulatory commission or agreement state or licensing state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-22. Training for an authorized nuclear pharmacist. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

1. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed seven hundred hours in a structured educational program consisting of both:

   (1) Didactic training in the following areas:

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

      (d) Chemistry of radioactive material for medical use; and

      (e) Radiation biology; and

   (2) Supervised practical experience in a nuclear pharmacy involving:

      (a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid medical events in the administration of radioactive material; and

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

b. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-23. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

1. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a United States nuclear regulatory commission or agreement state or licensing state license or a permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope licensee or master material license permit or by a master material license permittee of broad scope before September 1, 2003, need not comply with the training requirements of section 33-10-07.1-20 (training for radiation safety officer), 33-10-07.1-21 (training for an authorized medical physicist), or 33-10-07.1-22 (training for an authorized nuclear pharmacist), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the United States nuclear regulatory commission or an agreement state or a licensing state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee before September 1, 2003, who perform only those medical

uses for which they were authorized on that date need not comply with the training requirements in sections 33-10-07.1-35 through 33-10-07.1-75.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-24. Recentness of training. The training and experience specified in this chapter must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

History: Effective Marcy 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-25. Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material.

1. For direct measurements performed in accordance with section 33-10-07.1-27 (determination of dosages of unsealed radioactive material for medical use), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

2. A licensee shall calibrate the instrumentation required in subsection 1 in accordance with nationally recognized standards or the manufacturer's instructions.

3. A licensee shall retain a record of each instrument calibration required by this section in accordance with section 33-10-07.1-94 (records of calibrations of instruments used to measure the activity of unsealed radioactive material).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-26. Calibration of survey instruments.

1. A licensee shall calibrate the survey instruments used to show compliance with this chapter and chapter 33-10-04.1 (standards for protection against radiation) before first use, annually, and following a repair that affects the calibration. A licensee shall:

   a. Calibrate all scales with readings up to ten millisieverts [1000 millirems] per hour with a radiation source;

b. Calibrate two separated readings on each scale or decade that will be used to show compliance; and

c. Conspicuously note on the instrument the date of calibration.

2. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than twenty percent.

3. A licensee shall retain a record of each survey instrument calibration in accordance with section 33-10-07.1-95 (records of radiation survey instrument calibrations).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-27. Determination of dosages of unsealed radioactive material for medical use.

1. A licensee shall determine and record the activity of each dosage before medical use.

2. For a unit dosage, this determination must be made by:

a. Direct measurement of radioactivity; or

b. A decay correction, based on the activity or activity concentration determined by:

(1) A manufacturer or preparer licensed under subdivision i (manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under this chapter) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

(2) A United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the United States food and drug administration.

3. For other than unit dosages, this determination must be made by:

a. Direct measurement of radioactivity;

b. Combination of measurement of radioactivity and mathematical calculations; or

c. Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under subdivision i (manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under this chapter) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state.

4. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty percent.

5. A licensee shall retain a record of the dosage determination required by this section in accordance with section 33-10-07.1-96 (records of dosages of unsealed radioactive material for medical use).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-28. Authorization for calibration, transmission, and reference sources. Any person authorized by section 33-10-07.1-07 (license required) for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

1. Sealed sources, not exceeding one thousand one hundred ten megabecquerels [30 millicuries] each, manufactured and distributed by a person licensed under subdivision j (manufacture and distribution of sources or devices containing radioactive material for medical use) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state.

2. Sealed sources, not exceeding one thousand one hundred ten megabecquerels [30 millicuries] each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under subdivision j (manufacture and distribution of sources or devices containing radioactive material for medical use) of subsection 5 of section 33-10-03-05, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

3. Any radioactive material with a half-life not longer than one hundred twenty days in individual amounts not to exceed five hundred sixty megabecquerels [15 millicuries].

4. Any radioactive material with a half-life longer than one hundred twenty days in individual amounts not to exceed the smaller of seven thousand four hundred kilobecquerels [200 microcuries] or one thousand times the quantities in schedule F (criteria related to financial assurance and decommissioning) of chapter 33-10-03.

5. Technetium-99m in amounts as needed.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-29. Requirements for possession of sealed sources and brachytherapy sources.

1. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

2. A licensee in possession of a sealed source shall:

   a. Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

   b. Test the source for leakage at intervals not to exceed six months or at other intervals approved by the United States nuclear regulatory commission or an agreement state or a licensing state in the sealed source and device registry.

3. To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of one hundred eighty-five becquerels [.005 microcurie] of radioactive material in the sample.

4. A licensee shall retain leak test records in accordance with subsection 1 of section 33-10-07.1-97 (records of leak tests and inventory of sealed sources and brachytherapy sources).

5. If the leak test reveals the presence of one hundred eighty-five becquerels [.005 microcurie] or more of removable contamination, the licensee shall:

   a. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the

requirements in chapters 33-10-03 (licensing of radioactive material) and 33-10-04.1 (standards for protection against radiation); and

b. File a report within five days of the leak test in accordance with section 33-10-07.1-121 (report of a leaking source).

6. A licensee need not perform a leak test on the following sources:

a. Sources containing only radioactive material with a half-life of less than thirty days;

b. Sources containing only radioactive material as a gas;

c. Sources containing three thousand seven hundred kilobecquerels [100 microcuries] or less of beta-emitting or gamma-emitting material or three hundred seventy kilobecquerels [10 microcuries] or less of alpha-emitting material;

d. Seeds of iridium-192 encased in nylon ribbon; and

e. Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.

7. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semiannual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with subsection 2 of section 33-10-07.1-97 (records of leak tests and inventory of sealed sources and brachytherapy sources).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-30. Labeling of vials and syringes. Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-31. Surveys of ambient radiation exposure rate.

1. In addition to the surveys required by chapter 33-10-04.1 (standards for protection against radiation), a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

2. A licensee does not need to perform the surveys required by subsection 1 in an area where patients or human research subjects are confined when they cannot be released under section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material).

3. A licensee shall retain a record of each survey in accordance with section 33-10-07.1-98 (records of surveys for ambient radiation exposure rate).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-32. Release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts [500 millirems]. (United States nuclear regulatory commission publication NUREG-1556, volume 9, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five millisieverts [500 millirems].)

2. A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert [100 millirems]. If the total effective dose equivalent to a nursing infant or child could exceed one millisievert [100 millirems] assuming there were no interruption of breast-feeding, the instructions must also include:

   a. Guidance on the interruption or discontinuation of breast-feeding; and

b. Information on the potential consequences, if any, of failure to follow the guidance.

3. A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with subsection 1 of section 33-10-07.1-99 (records of the release of individuals containing unsealed radioactive material or implants containing radioactive material).

4. The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with subsection 2 of section 33-10-07.1-99 (records of the release of individuals containing unsealed radioactive material or implants containing radioactive material).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-33. Provision of mobile medical service.

1. A licensee providing mobile medical service shall:

   a. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

   b. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function must include a constancy check;

   c. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

   d. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in chapter 33-10-04.1 (standards for protection against radiation).

2. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

3. A licensee providing mobile medical services shall retain the letter required in subdivision a of subsection 1 and the record of each survey required in subdivision d of subsection 1 in accordance with

subsections 1 and 2 of section 33-10-07.1-100 (records of mobile medical services), respectively.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-34. Decay-in-storage.

1. A licensee may hold radioactive material with a physical half-life of less than one hundred twenty days for decay-in-storage before disposal without regard to its radioactivity if it:

   a. Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

   b. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

2. A licensee shall retain a record of each disposal permitted under subsection 1 in accordance with section 33-10-07.1-101 (records of decay-in-storage).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-35. Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required. Except for quantities that require a written directive under subsection 2 of section 33-10-07.1-17 (written directives), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

1. Obtained from a manufacturer or preparer licensed under subdivision i (manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under this chapter) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state;

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in section 33-10-07.1-40 (training for imaging and localization studies) or 33-10-07.1-44 (training for use of unsealed radioactive material

for which a written directive is required), or an individual under the supervision of either as specified in section 33-10-07.1-16 (supervision);

3. Obtained from and prepared by a United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the United States food and drug administration; or

4. Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the United States food and drug administration.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-36. Training for uptake, dilution, and excretion studies. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state;

2. Is an authorized user under section 33-10-07.1-40 (training for imaging and localization studies) or 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

3. a. Has completed sixty hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in section 33-10-07.1-36 (training for uptake, dilution, and excretion studies), section 33-10-07.1-40 (training for imaging and localization studies), or section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, involving:

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

(b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

b. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in section 33-10-07.1-36 (training for uptake, dilution, and excretion studies), section 33-10-07.1-40 (training for imaging and localization studies), or section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, that the individual has satisfactorily completed the requirements in subdivision a and has achieved a level of competency sufficient to function independently

as an authorized user for the medical uses authorized under section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-37. Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required. Except for quantities that require a written directive under subsection 2 of section 33-10-07.1-17 (written directives), a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

1. Obtained from a manufacturer or preparer licensed under subdivision i (manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under this chapter) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state;

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in section 33-10-07.1-40 (training for imaging and localization studies) or 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), or an individual under the supervision of either as specified in section 33-10-07.1-16 (supervision);

3. Obtained from and prepared by a United States nuclear regulatory commission or agreement state or licensing state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the United States food and drug administration; or

4. Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the United States food and drug administration.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-38. Permissible molybdenum-99 concentrations.

1. A licensee may not administer to humans a radiopharmaceutical that contains more than one hundred fifty becquerels of molybdenum-99 per

megabecquerel of technetium-99m [.15 microcurie of molybdenum-99 per millicurie of technetium-99m].

2. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection 1.

3. If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with section 33-10-07.1-102 (records of molybdenum-99 concentrations).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-39. Permissible aluminum ion concentrations.

1. A licensee may not administer to humans a radiopharmaceutical that contains more than ten micrograms of aluminum per milliliter of technetium-99m.

2. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the aluminum ion concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection 1.

3. If a licensee is required to measure the aluminum ion concentration, the licensee shall retain a record of each measurement in accordance with section 33-10-07.1-103 (records of aluminum ion concentrations).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-40. Training for imaging and localization studies. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under section 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required) to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state;

2. Is an authorized user under section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required) or equivalent requirements of the United States nuclear regulatory commmission, an agreement state, or a licensing state; or

3. a. Has completed seven hundred hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Work experience, under the supervision of an authorized user, who meets the requirements in this section or section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, involving:

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

(b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

b. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in this section or section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, that the individual has satisfactorily completed the requirements in subdivision a of subsection 3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under sections 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) and 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-41. Use of unsealed radioactive material for which a written directive is required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

1. Obtained from a manufacturer or preparer licensed under subdivision i (manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under this chapter) of subsection 5 of section 33-10-03-05 or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state;

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in section 33-10-07.1-40 (training for imaging and localization studies) or 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), or an individual under the supervision of either as specified in section 33-10-07.1-16 (supervision);

3. Obtained from and prepared by a United States nuclear regulatory commission or agreement state or licensing state licensee for use

in research in accordance with an investigational new drug protocol accepted by the United States food and drug administration; or

4. Prepared by the licensee for use in research in accordance with an investigational new drug protocol accepted by the United States food and drug administration.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-42. Safety instruction for the use of unsealed radioactive material for which a written directive is required. In addition to the requirements of subsection 2 (instructions to workers) of section 33-10-10-02:

1. A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material). To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

   a. Patient or human research subject control;

   b. Visitor control, including:

      (1) Routine visitation to hospitalized individuals in accordance with paragraph 1 of subdivision a of subsection 1 of section 33-10-04.1-07 (radiation dose limits for individual members of the public); and

      (2) Visitation authorized in accordance with subdivision c of subsection 1 of section 33-10-04.1-07 (radiation dose limits for individual members of the public);

   c. Contamination control;

   d. Waste control; and

   e. Notification of the radiation safety officer, or that person's designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

2. A licensee shall retain a record of individuals receiving instruction in accordance with section 33-10-07.1-104 (records of safety instruction).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-43. Safety precautions for the use of unsealed radioactive material for which a written directive is required.

1. For each patient or human research subject who cannot be released under section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material), a licensee shall:

   a. Quarter the patient or the human research subject either in:

      (1) A private room with a private sanitary facility; or

      (2) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material);

   b. Visibly post the patient's or the human research subject's room with a "radioactive materials" sign;

   c. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

   d. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

2. A licensee shall notify the radiation safety officer, or that person's designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-44. Training for use of unsealed radioactive material for which a written directive is required. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under section 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required) to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed seven hundred hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

   (1) Classroom and laboratory training in the following areas:

      (a) Radiation physics and instrumentation;

      (b) Radiation protection;

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

      (d) Chemistry of radioactive material for medical use; and

      (e) Radiation biology; and

   (2) Work experience, under the supervision of an authorized user who meets the requirements in subsections 1 or 2, or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A supervising authorized user, who meets the requirements in subsection 2, must have experience in administering dosages in the same dosage category or categories (i.e., items 1, 2, 3, or 4 of subparagraph g) as the individual requesting authorized user status. The work experience must involve:

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

      (b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(f) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(g) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

[1] Oral administration of less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131;

[2] Oral administration of greater than one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131 (Note: experience with at least three of these cases also satisfies the requirement in item 1 for oral administration of less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries].);

[3] Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than one hundred fifty kilo electron volts; and

[4] Parenteral administration of any other radionuclide; and

b. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under section 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required). The written certification must be signed by a preceptor authorized user who meets the requirements in subsections 1 or 2, or equivalent

requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. The preceptor authorized user, who meets the requirements in subsection 2, must have experience in administering dosages in the same dosage category or categories (i.e., items 1, 2, 3, or 4 of subparagraph g of paragraph 2 of subdivision a of subsection 2) as the individual requesting authorized user status.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 20-20.1-04

33-10-07.1-45. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries]. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries], to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state;

2. Is an authorized user under subsections 1 or 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required); is an authorized user for the oral administration of sodium iodide I-131 requiring a written directive; is an authorized user under section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]); or is an authorized user under equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

3. a. Has successfully completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

   (1) Radiation physics and instrumentation;

   (2) Radiation protection;

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

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology;

b. Has work experience, under the supervision of an authorized user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), this section, section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A supervising authorized user who meets the requirements in subsection 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), must have experience in oral administration of sodium iodide I-131 requiring a written directive. The work experience must involve:

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

(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

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

(6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131; and

c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 3 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under section 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required). The written certification must be signed by a preceptor authorized

user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), this section, section 33-10-07.1-46 (training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]), or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A preceptor authorized user, who meets the requirements in subsection 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), must have experience in oral administration of sodium iodide I-131 requiring a written directive.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-46. Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries]. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than one thousand two hundred twenty megabecquerels [33 millicuries], to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 3 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. Is an authorized user under subsection 1 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required); subsection 2 of section 33-10-07.1-44 for the oral administration of greater than one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131 requiring a written directive; or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

3. a. Has successfully completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

   (1) Radiation physics and instrumentation;

   (2) Radiation protection;

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

(4) Chemistry of radioactive material for medical use; and

(5) Radiation biology;

b. Has work experience, under the supervision of an authorized user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), this section, or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A supervising authorized user, who meets the requirements in subsection 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), must have experience in the oral administration of greater than one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131 requiring a written directive. The work experience must involve:

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

(2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

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

(6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131; and

c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 3 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under section 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required). The written certification must be signed by a preceptor

authorized user who meets the requirements in subsections 1 or 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), this section, or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state. A preceptor authorized user, who meets the requirements in subsection 2 of section 33-10-07.1-44 (training for use of unsealed radioactive material for which a written directive is required), must have experience in oral administration of greater than one thousand two hundred twenty megabecquerels [33 millicuries] of sodium iodide I-131 requiring a written directive.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-47. Use of sources for manual brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

1. As approved in the sealed source and device registry; or

2. In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of subsection 1 of section 33-10-07.1-19 (suppliers for sealed sources or devices for medical use) are met.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-48. Surveys after source implant and removal.

1. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

2. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

3. A licensee shall retain a record of the surveys required by subsections 1 and 2 in accordance with section 33-10-07.1-105 (records of surveys after source implant and removal).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-49. Brachytherapy sources accountability.

1. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

2. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

3. A licensee shall maintain a record of the brachytherapy source accountability in accordance with section 33-10-07.1-106 (records of brachytherapy source accountability).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-50. Safety instruction for the use of sources for manual brachytherapy. In addition to the requirements of subsection 2 (instructions to workers) of section 33-10-10-02:

1. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material). To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the:

   a. Size and appearance of the brachytherapy sources;

   b. Safe handling and shielding instructions;

   c. Patient or human research subject control;

   d. Visitor control, including both:

      (1) Routine visitation of hospitalized individuals in accordance with paragraph 1 of subdivision a of subsection 1 of section 33-10-04.1-07 (radiation dose limits for individual members of the public); and

      (2) Visitation authorized in accordance with subdivision c of subsection 1 of section 33-10-04.1-07 (radiation dose limits for individual members of the public); and

   e. Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

2. A licensee shall retain a record of individuals receiving instruction in accordance with section 33-10-07.1-104 (records of safety instruction).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-51. Safety precautions for the use of sources for manual brachytherapy.

1. For each patient or human research subject who is receiving brachytherapy and cannot be released under section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material), a licensee shall:

   a. Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

   b. Visibly post the patient's or human research subject's room with a "radioactive materials" sign; and

   c. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

2. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

   a. Dislodged from the patient; and

   b. Lodged within the patient following removal of the source applicators.

3. A licensee shall notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-52. Calibration measurements of brachytherapy sources.

1. Before the first medical use of a brachytherapy source on or after September 1, 2003, a licensee shall have:

   a. Determined the source output or activity using a dosimetry system that meets the requirements of subsection 1 of section 33-10-07.1-64 (dosimetry equipment);

b. Determined source positioning accuracy within applicators; and

c. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subdivisions a and b of subsection 1.

2. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American association of physicists in medicine that are made in accordance with subsection 1.

3. A licensee shall mathematically correct the outputs or activities determined in subsection 1 for physical decay at intervals consistent with one percent physical decay.

4. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-107 (records of calibration measurements of brachytherapy sources).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-53. Decay of strontium-90 sources for ophthalmic treatments.

1. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under section 33-10-07.1-52 (calibration measurements of brachytherapy sources).

2. A licensee shall retain a record of the activity of each strontium-90 source in accordance with section 33-10-07.1-108 (records of decay of strontium-90 sources for ophthalmic treatments).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-54. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays; and

4. The accuracy of the software used to determine sealed source positions from radiographic images.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-55. Training for use of manual brachytherapy sources. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under section 33-10-07.1-47 (use of sources for manual brachytherapy) to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(1) Two hundred hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(2) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, at a medical institution, involving:

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

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a medical event involving the use of radioactive material; or

(f) Using emergency procedures to control radioactive material;

b. Has obtained three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, as part of a formal training program approved by the residency review committee for radiation oncology of the accreditation council for graduate medical education or the committee on postdoctoral training of the american osteopathic association. This experience may be obtained concurrently with the supervised work experience required by paragraph 2 of subdivision a of subsection 2; and

c. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 2 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under section 33-10-07.1-47 (use of sources for manual brachytherapy).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-56. Training for ophthalmic use of strontium-90. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

1. Is an authorized user under section 33-10-07.1-55 (training for use of manual brachytherapy sources) or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state; or

2. a. Has completed twenty-four hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology;

b. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Followup and review of each individual's case history; and

c. Has obtained written certification, signed by a preceptor authorized user who meets the requirements in section 33-10-07.1-55 (training for use of manual brachytherapy sources), this section, or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, that the individual has satisfactorily completed the requirements in subsections 1 and 2 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-57. Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the sealed source and device registry.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-58. Training for use of sealed sources for diagnosis. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under section 33-10-07.1-57 (use of sealed sources for diagnosis) to be a physician, dentist, or podiatrist who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. Has had eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

   a. Radiation physics and instrumentation;

   b. Radiation protection;

   c. Mathematics pertaining to the use and measurement of radioactivity;

   d. Radiation biology; and

   e. Training in the use of the device for the uses requested.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-59. Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. A licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the sealed source and device registry; or

2. In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of subsection 1 of section

33-10-07.1-19 (suppliers for sealed sources or devices for medical use) are met.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-60. Surveys of patients and human research subjects treated with a remote afterloader unit.

1. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that each source has been removed from the patient or human research subject and returned to the safe shielded position.

2. A licensee shall retain a record of these surveys in accordance with section 33-10-07.1-105 (records of surveys after source implant and removal).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-61. Installation, maintenance, adjustment, and repair.

1. Only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of the unit or a source.

2. Except for low dose-rate remote afterloader units, only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

3. For a low dose-rate remote afterloader unit, only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

4. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with section 33-10-07.1-109 (records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-62. Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. A licensee shall:

   a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

   b. Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with a source;

   c. Prevent dual operation of more than one radiation-producing device in a treatment room if applicable; and

   d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place a source in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

      (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

      (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

      (3) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

2. A copy of the procedures required by subdivision d of subsection 1 must be physically located at the unit console.

3. A licensee shall post instructions at the unit console to inform the operator of:

   a. The location of the procedures required by subdivision d of subsection 1; and

   b. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

4. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

   a. The procedures identified in subdivision d of subsection 1; and

   b. The operating procedures for the unit.

5. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

6. A licensee shall retain a record of individuals receiving instruction required by subsection 4, in accordance with section 33-10-07.1-104 (records of safety instruction).

7. A licensee shall retain a copy of the procedures required by subdivision d of subsection 1 and subdivision b of subsection 4 in accordance with section 33-10-07.1-110 (records of safety procedures).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-63. Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. A licensee shall control access to the treatment room by a door at each entrance.

2. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

   a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

   b. Cause each source to be shielded when an entrance door is opened; and

c. Prevent any source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

3. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

4. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

5. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

6. In addition to the requirements specified in subsections 1 through 5, a licensee shall:

a. For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(1) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(2) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove each source applicator in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

b. For high dose-rate remote afterloader units, require:

(1) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(2) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

c. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

d. Notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

7. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

a. Remaining in the unshielded position; or

b. Lodged within the patient following completion of the treatment.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-64. Dosimetry equipment.

1. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

a. The system must have been calibrated using a system or source traceable to the national institute of science and technology and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by the american association of physicists in medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

b. The system must have been calibrated within the previous four years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past twenty-four months by the national institute of science and technology or by a calibration laboratory accredited by the american association of physicists in medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

2. The licensee shall have a dosimetry system available for use for spot check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection 1. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot check system may be the same system used to meet the requirement in subsection 1.

3. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with section 33-10-07.1-111 (records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-65. Full calibration measurements on teletherapy units.

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

   a. Before the first medical use of the unit;

   b. Before medical use under the following conditions:

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

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

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

   c. At intervals not exceeding one year.

2. To satisfy the requirement of subsection 1, full calibration measurements must include determination of:

   a. The output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

   b. The coincidence of the radiation field and the field indicated by the light beam localizing device;

c. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

d. Timer accuracy and linearity over the range of use;

e. On-off error; and

f. The accuracy of all distance measuring and localization devices in medical use.

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 (dosimetry equipment) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision a of subsection 2 may be made using a dosimetry system that indicates relative dose rates.

4. A licensee shall make full calibration measurements required by subsection 1 in accordance with published protocols accepted by nationally recognized bodies.

5. A licensee shall mathematically correct the outputs determined in subdivision a of subsection 2 for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

6. Full calibration measurements required by subsection 1 and physical decay corrections required by subsection 5 must be performed by the authorized medical physicist.

7. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-112 (records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-66. Full calibration measurements on remote afterloader units.

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

a. Before the first medical use of the unit;

b. Before medical use under the following conditions:

(1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility;

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

(3) At intervals not exceeding one-quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy-five days; and

(4) At intervals not exceeding one year for low dose-rate remote afterloader units.

2. To satisfy the requirement of subsection 1, full calibration measurements must include, as applicable, determination of:

a. The output within plus or minus five percent;

b. Source positioning accuracy to within plus or minus one millimeter;

c. Source retraction with backup battery upon power failure;

d. Length of the source transfer tubes;

e. Timer accuracy and linearity over the typical range of use;

f. Length of the applicators; and

g. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 (dosimetry equipment) to measure the output.

4. A licensee shall make full calibration measurements required by subsection 1 in accordance with published protocols accepted by nationally recognized bodies.

5. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection 2, a licensee shall perform an autoradiograph of each source to verify inventory and source arrangement at intervals not exceeding one-quarter.

6. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections 1 through 5.

7. A licensee shall mathematically correct the outputs determined in subdivision a of subsection 2 for physical decay at intervals consistent with one percent physical decay.

8. Full calibration measurements required by subsection 1 and physical decay corrections required by subsection 7 must be performed by the authorized medical physicist.

9. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-112 (records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-67. Full calibration measurements on gamma stereotactic radiosurgery units.

1. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

   a. Before the first medical use of the unit;

   b. Before medical use under the following conditions:

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

      (2) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

      (3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

   c. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

2. To satisfy the requirement of subsection 1, full calibration measurements must include determination of:

   a. The output within plus or minus three percent;

   b. Relative helmet factors;

   c. Isocenter coincidence;

   d. Timer accuracy and linearity over the range of use;

e. On-off error;

f. Trunnion centricity;

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

h. Helmet microswitches;

i. Emergency timing circuits; and

j. Stereotactic frames and localizing devices (trunnions).

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 (dosimetry equipment) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision a of subsection 2 may be made using a dosimetry system that indicates relative dose rates.

4. A licensee shall make full calibration measurements required by subsection 1 in accordance with published protocols accepted by nationally recognized bodies.

5. A licensee shall mathematically correct the outputs determined in subdivision a of subsection 2 at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

6. Full calibration measurements required by subsection 1 and physical decay corrections required by subsection 5 must be performed by the authorized medical physicist.

7. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-112 (records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-68. Periodic spot checks for teletherapy units.

1. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

a. Timer accuracy and timer linearity over the range of use;

b. On-off error;

c. The coincidence of the radiation field and the field indicated by the light beam localizing device;

d. The accuracy of all distance measuring and localization devices used for medical use;

e. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 2 of section 33-10-07.1-64 (dosimetry equipment); and

f. The difference between the measurement made in subdivision e of subsection 1 and the anticipated output, expressed as a percentage of the anticipated output, i.e., the value obtained at last full calibration corrected mathematically for physical decay.

2. A licensee shall perform measurements required by subsection 1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

3. A licensee shall have the authorized medical physicist review the results of each spot check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

4. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

a. Electrical interlocks at each teletherapy room entrance;

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

c. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

d. Viewing and intercom systems;

e. Treatment room doors from inside and outside the treatment room; and

f. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

5. If the results of the checks required in subsection 4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

6. A licensee shall retain a record of each spot check required by subsections 1 and 4, and a copy of the procedures required by subsection 2, in accordance with section 33-10-07.1-113 (records of periodic spot checks for teletherapy units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-69. Periodic spot checks for remote afterloader units.

1. A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

   a. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

   b. Before each patient treatment with a low dose-rate remote afterloader unit; and

   c. After each source installation.

2. A licensee shall perform the measurements required by subsection 1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

3. A licensee shall have the authorized medical physicist review the results of each spot check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

4. To satisfy the requirements of subsection 1, spot checks must, at a minimum, assure proper operation of:

   a. Electrical interlocks at each remote afterloader unit room entrance;

   b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

   c. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

d. Emergency response equipment;

e. Radiation monitors used to indicate the source position;

f. Timer accuracy;

g. Clock date and time in the unit's computer; and

h. Decayed source activity in the unit's computer.

5. If the results of the spot checks required in subsection 4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

6. A licensee shall retain a record of each spot check required by subsection 4 and a copy of the procedures required by subsection 2 in accordance with section 33-10-07.1-114 (records of periodic spot checks for remote afterloader units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-70. Periodic spot checks for gamma stereotactic radiosurgery units.

1. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks of each gamma stereotactic radiosurgery facility and on each unit:

   a. Monthly;

   b. Before the first use of the unit on a given day; and

   c. After each source installation.

2. A licensee shall:

   a. Perform the measurements required by subsection 1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

   b. Have the authorized medical physicist review the results of each spot check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

3. To satisfy the requirements of subdivision a of subsection 1, spot checks must, at a minimum:

   a. Assure proper operation of:

      (1) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

      (2) Helmet microswitches;

      (3) Emergency timing circuits; and

      (4) Stereotactic frames and localizing devices (trunnions).

   b. Determine:

      (1) The output for one typical set of operating conditions measured with the dosimetry system described in subsection 2 of section 33-10-07.1-64 (dosimetry equipment);

      (2) The difference between the measurement made in paragraph 1 and the anticipated output, expressed as a percentage of the anticipated output, i.e., the value obtained at last full calibration corrected mathematically for physical decay;

      (3) Source output against computer calculation;

      (4) Timer accuracy and linearity over the range of use;

      (5) On-off error; and

      (6) Trunnion centricity.

4. To satisfy the requirements of subdivisions b and c of subsection 1, spot checks must assure proper operation of:

   a. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

   b. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

   c. Viewing and intercom systems;

   d. Timer termination;

   e. Radiation monitors used to indicate room exposures; and

f. Emergency off buttons.

5. A licensee shall arrange for the repair of any system identified in subsection 3 that is not operating properly as soon as possible.

6. If the results of the checks required in subsection 4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7. A licensee shall retain a record of each check required by subsections 3 and 4 and a copy of the procedures required by subsection 2 in accordance with section 33-10-07.1-115 (records of periodic spot checks for gamma stereotactic radiosurgery units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-71. Additional technical requirements for mobile remote afterloader units.

1. A licensee providing mobile remote afterloader service shall:

   a. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

   b. Account for all sources before departure from a client's address of use.

2. In addition to the periodic spot checks required by section 33-10-07.1-69 (periodic spot checks for remote afterloader units), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, spot checks must be made to verify the operation of:

   a. Electrical interlocks on treatment area access points;

   b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

   c. Viewing and intercom systems;

   d. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

   e. Radiation monitors used to indicate room exposures;

f. Source positioning (accuracy); and

g. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

3. In addition to the requirements for spot checks in subsection 2, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

4. If the results of the spot checks required in subsection 2 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

5. A licensee shall retain a record of each spot check required by subsection 2 in accordance with section 33-10-07.1-116 (records of additional technical requirements for mobile remote afterloader units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-72. Radiation surveys.

1. In addition to the survey requirement in subsection 1 of section 33-10-04.1-09 (survey and monitoring), a person licensed under sections 33-10-07.1-59 through 33-10-07.1-75 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the sealed source and device registry.

2. The licensee shall make the survey required by subsection 1 at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of the unit or a source.

3. A licensee shall retain a record of the radiation surveys required by subsection 1 in accordance with section 33-10-07.1-117 (records of surveys of therapeutic treatment units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-73. Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

1. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

2. This inspection and servicing may only be performed by persons specifically licensed to do so by the United States nuclear regulatory commission or an agreement state or a licensing state.

3. A licensee shall keep a record of the inspection and servicing in accordance with section 33-10-07.1-118 (records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-74. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays;

4. The accuracy of the software used to determine sealed source positions from radiographic images; and

5. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-75. Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an authorized user of a sealed source for a use authorized under section 33-10-07.1-59 (use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit) to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(1) Two hundred hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology; and

(2) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state at a medical institution, involving:

(a) Reviewing full calibration measurements and periodic spot checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a medical event involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered;

b. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this section or equivalent requirements of the

United States nuclear regulatory commission, an agreement state, or a licensing state, as part of a formal training program approved by the residency review committee for radiation oncology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American osteopathic association. This experience may be obtained concurrently with the supervised work experience required by paragraph 2 of subdivision a of subsection 2; and

c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 2 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-76. Radiation safety officer. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in section 33-10-07.1-14 (authority and responsibilities for the radiation protection program) to be an individual who:

1. Is certified by the:

   a. American board of health physics in comprehensive health physics;

   b. American board of radiology;

   c. American board of nuclear medicine;

   d. American board of science in nuclear medicine;

   e. Board of pharmaceutical specialties in nuclear pharmacy;

   f. American board of medical physics in radiation oncology physics;

   g. Royal college of physicians and surgeons of Canada in nuclear medicine;

h. American osteopathic board of radiology; or

i. American osteopathic board of nuclear medicine;

2. Has had classroom and laboratory training and experience as follows:

a. Two hundred hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(5) Radiopharmaceutical chemistry; and

b. One year of full-time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the radiation safety officer on a United States nuclear regulatory commission or agreement state or licensing state license that authorizes the medical use of radioactive material; or

3. Is an authorized user identified on the licensee's license.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-77. Training for uptake, dilution, and excretion studies. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of a radiopharmaceutical in subsection 1 of section 33-10-07.1-35 (use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required) to be a physician who:

1. Is certified in:

a. Nuclear medicine by the American board of nuclear medicine;

b. Diagnostic radiology by the American board of radiology;

c. Diagnostic radiology or radiology by the American osteopathic board of radiology;

d. Nuclear medicine by the royal college of physicians and surgeons of Canada; or

e. American osteopathic board of nuclear medicine in nuclear medicine;

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals and supervised clinical experience as follows:

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

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(5) Radiopharmaceutical chemistry; and

b. Twenty hours of supervised clinical experience under the supervision of an authorized user and that includes:

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

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

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

(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(5) Patient or human research subject followup; or

3. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the accreditation council for graduate medical education and that included

classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 2.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-78. Training for imaging and localization studies. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in subsection 1 of section 33-10-07.1-37 (use of unsealed radioactive material for imaging and localization studies for which a written directive is not required) to be a physician who:

1. Is certified in:

   a. Nuclear medicine by the American board of nuclear medicine;

   b. Diagnostic radiology by the American board of radiology;

   c. Diagnostic radiology or radiology by the American osteopathic board of radiology;

   d. Nuclear medicine by the royal college of physicians and surgeons of Canada; or

   e. American osteopathic board of nuclear medicine in nuclear medicine;

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

   a. Two hundred hours of classroom and laboratory training that includes:

      (1) Radiation physics and instrumentation;

      (2) Radiation protection;

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

      (4) Radiopharmaceutical chemistry; and

      (5) Radiation biology;

b. Five hundred hours of supervised work experience under the supervision of an authorized user that includes:

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

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

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

(4) Using administrative controls to prevent a medical event involving radioactive material;

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

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

c. Five hundred hours of supervised clinical experience under the supervision of an authorized user that includes:

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

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

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

(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(5) Patient or human research subject followup; or

3. Has successfully completed a six-month training program in nuclear medicine that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory

training, work experience, and supervised clinical experience in all the topics identified in subsection 2.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-79. Training for therapeutic use of unsealed radioactive material. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of radiopharmaceuticals in section 33-10-07.1-41 (use of unsealed radioactive material for which a written directive is required) to be a physician who:

1. Is certified by:

   a. The American board of nuclear medicine;

   b. The American board of radiology in radiology, therapeutic radiology, or radiation oncology;

   c. The royal college of physicians and surgeons of Canada in nuclear medicine; or

   d. The American osteopathic board of radiology after 1984; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals and supervised clinical experience as follows:

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

      (1) Radiation physics and instrumentation;

      (2) Radiation protection;

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

      (4) Radiation biology; and

   b. Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

      (1) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals; and

(2) Use of iodine-131 for treatment of thyroid carcinoma in three individuals.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-80. Training for treatment of hyperthyroidism. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

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

   a. Radiation physics and instrumentation;

   b. Radiation protection;

   c. Mathematics pertaining to the use and measurement of radioactivity; and

   d. Radiation biology; and

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

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-81. Training for treatment of thyroid carcinoma. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

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

   a. Radiation physics and instrumentation;

   b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three individuals.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-82. Training for use of brachytherapy sources. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of a brachytherapy source listed in section 33-10-07.1-47 (use of sources for manual brachytherapy) for therapy to be a physician who:

1. Is certified in:

   a. Radiology, therapeutic radiology, or radiation oncology by the American board of radiology;

   b. Radiation oncology by the American osteopathic board of radiology;

   c. Radiology, with specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or

   d. Therapeutic radiology by the Canadian royal college of physicians and surgeons; or

2. Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

   a. Two hundred hours of classroom and laboratory training that includes:

      (1) Radiation physics and instrumentation;

      (2) Radiation protection;

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

(4) Radiation biology;

b. Five hundred hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

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

(2) Checking survey meters for proper operation;

(3) Preparing, implanting, and removing sealed sources;

(4) Maintaining running inventories of material on hand;

(5) Using administrative controls to prevent a medical event involving radioactive material; and

(6) Using emergency procedures to control radioactive material; and

c. Three years of supervised clinical experience that includes one year in a formal training program approved by the residency review committee for radiology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American osteopathic association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(1) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment and any limitations or contraindications;

(2) Selecting the proper brachytherapy sources and dose and method of administration;

(3) Calculating the dose; and

(4) Postadministration followup and review of case histories in collaboration with the authorized user.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-83. Training for ophthalmic use of strontium-90. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of only strontium-90 for ophthalmic

radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

1. Twenty-four hours of classroom and laboratory training that includes:

   a. Radiation physics and instrumentation;

   b. Radiation protection;

   c. Mathematics pertaining to the use and measurement of radioactivity; and

   d. Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

   a. Examination of each individual to be treated;

   b. Calculation of the dose to be administered;

   c. Administration of the dose; and

   d. Followup and review of each individual's case history.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-84. Training for use of sealed sources for diagnosis. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of a sealed source in a device listed in section 33-10-07.1-57 (use of sealed sources for diagnosis) to be a physician, dentist, or podiatrist who:

1. Is certified in:

   a. Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American board of radiology;

   b. Nuclear medicine by the American board of nuclear medicine;

c. Diagnostic radiology or radiology by the American osteopathic board of radiology; or

d. Nuclear medicine by the royal college of physicians and surgeons of Canada; or

2. Has had eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

b. Radiation biology;

c. Radiation protection; and

d. Training in the use of the device for the uses requested.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-85. Training for use of therapeutic medical devices. Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized user of a sealed source listed in section 33-10-07.1-59 (use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit) to be a physician who:

1. Is certified in:

a. Radiology, therapeutic radiology, or radiation oncology by the American board of radiology;

b. Radiation oncology by the American osteopathic board of radiology;

c. Radiology, with specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or

d. Therapeutic radiology by the Canadian royal college of physicians and surgeons; or

2. Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to

the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows:

a. Two hundred hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology;

b. Five hundred hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(1) Reviewing of the full calibration measurements and periodic spot checks;

(2) Preparing treatment plans and calculating treatment times;

(3) Using administrative controls to prevent medical events;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

(5) Checking and using survey meters; and

c. Three years of supervised clinical experience that includes one year in a formal training program approved by the residency review committee for radiology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American osteopathic association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(1) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

(2) Selecting the proper dose and how it is to be administered;

(3) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects'

progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reactions to radiation; and

(4) Postadministration followup and review of case histories.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-86. Training for an authorized medical physicist. The licensee shall require the authorized medical physicist to be an individual who:

1. Is certified by the American board of radiology in:

   a. Therapeutic radiological physics;

   b. Roentgen ray and gamma-ray physics;

   c. X-ray and radium physics; or

   d. Radiological physics;

2. Is certified by the American board of medical physics in radiation oncology physics; or

3. Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in sections 33-10-07.1-29 (requirements for possession of sealed sources and brachytherapy sources), 33-10-07.1-53 (decay of strontium-90 sources for ophthalmic treatments), 33-10-07.1-65 (full calibration measurements on teletherapy units), 33-10-07.1-66 (full calibration measurements on remote afterloader units), 33-10-07.1-67 (full calibration measurements on gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units), and 33-10-07.1-72 (radiation surveys), as applicable.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-87. Training for an authorized nuclear pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

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

2. a. Has completed seven hundred hours in a structured educational program consisting of both:

(1) Didactic training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

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

(a) Shipping, receiving, and performing related radiation surveys;

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

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid mistakes in the administration of radioactive material; and

(e) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

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

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-88. Training for experienced nuclear pharmacists. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in subdivision a of subsection 2 of section 33-10-07.1-87 (training for an authorized nuclear pharmacist) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (subdivision b of subsection 2 of section 33-10-07.1-87) and recentness of training (section 33-10-07.1-24) to qualify as an authorized nuclear pharmacist.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-89. Other medical uses of radioactive material or radiation from radioactive material. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in sections 33-10-07.1-35 through 33-10-07.1-75 if:

1. The applicant or licensee has submitted the information required by subsections 2 through 4 of section 33-10-07.1-08 (application for license, amendment, or renewal); and

2. The applicant or licensee has received written approval from the department in a license or license amendment and uses the material in accordance with the rules and specific conditions the department considers necessary for the medical use of the material.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-90. Records of authority and responsibilities for radiation protection programs.

1. A licensee shall retain a record of actions taken by the licensee's management in accordance with subsection 1 of section 33-10-07.1-14 (authority and responsibilities for the radiation protection program) for five years. The record must include a summary of the actions taken and a signature of licensee management.

2. The licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer as required by subsection 5 of section 33-10-07.1-14 (authority and responsibilities for the radiation protection program), and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by subsection 2 of section 33-10-07.1-14

(authority and responsibilities for the radiation protection program), for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-91. Records of radiation protection program changes. A licensee shall retain a record of each radiation protection program change made in accordance with subsection 1 of section 33-10-07.1-15 (radiation protection program changes) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-92. Records of written directives. A licensee shall retain a copy of each written directive as required by section 33-10-07.1-17 (written directives) for three years.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-93. Records for procedures for administrations requiring a written directive. A licensee shall retain a copy of the procedures required by subsection 1 of section 33-10-07.1-18 (procedures for administrations requiring a written directive) for the duration of the license.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-94. Records of calibrations of instruments used to measure the activity of unsealed radioactive material. A licensee shall maintain a record of instrument calibrations required by section 33-10-07.1-25 (possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material) for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-95. Records of radiation survey instrument calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by section 33-10-07.1-26 (calibration of survey instruments) for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-96. Records of dosages of unsealed radioactive material for medical use.

1. A licensee shall maintain a record of dosage determinations required by section 33-10-07.1-27 (determination of dosages of unsealed radioactive material for medical use) for three years.

2. The record must contain:

   a. The radiopharmaceutical;

   b. The patient's or human research subject's name, or identification number if one has been assigned;

   c. The prescribed dosage, the determined dosage, or a notation that the total activity is less than one thousand one hundred kilobecquerels [30 microcuries];

   d. The date and time of the dosage determination; and

   e. The name of the individual who determined the dosage.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-97. Records of leak tests and inventory of sealed sources and brachytherapy sources.

1. A licensee shall retain records of leak tests required by subsection 2 of section 33-10-07.1-29 (requirements for possession of sealed sources and brachytherapy sources) for three years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

2. A licensee shall retain records of the semiannual physical inventory of sealed sources and brachytherapy sources required by subsection 7 of section 33-10-07.1-29 (requirements for possession of sealed sources and brachytherapy sources) for three years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-98. Records of surveys for ambient radiation exposure rate. A licensee shall retain a record of each survey required by section 33-10-07.1-31 (surveys of ambient radiation exposure rate) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-99. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material), if the total effective dose equivalent is calculated by:

   a. Using the retained activity rather than the activity administered;

   b. Using an occupancy factor less than twenty-five hundredths at one meter;

   c. Using the biological or effective half-life; or

   d. Considering the shielding by tissue.

2. A licensee shall retain a record that the instructions required by subsection 2 of section 33-10-07.1-32 (release of individuals containing unsealed radioactive material or implants containing radioactive material) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts [500 millirems].

3. The records required by subsections 1 and 2 must be retained for three years after the date of release of the individual.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-100. Records of mobile medical services.

1. A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by subdivision a of subsection 1 of section 33-10-07.1-33 (provision of mobile medical service). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service.

2. A licensee shall retain the record of each survey required by subdivision d of subsection 1 of section 33-10-07.1-33 (provision of mobile medical service) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-101. Records of decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by section 33-10-07.1-34 (decay-in-storage), for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-102. Records of molybdenum-99 concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by subsection 2 of section 33-10-07.1-38 (permissible molybdenum-99 concentrations) for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of

molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-103. Records of aluminum ion concentrations. A licensee shall maintain a record of the aluminum ion concentration tests required by section 33-10-07.1-39 (permissible aluminum ion concentrations) for three years.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-104. Records of safety instruction. A licensee shall maintain a record of safety instructions required by sections 33-10-07.1-42 (safety instruction for the use of unsealed radioactive material for which a written directive is required), 33-10-07.1-50 (safety instruction for the use of sources for manual brachytherapy), and 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units) for three years. The record must include a list of the topics covered, the date of the instruction, the name of each attendee, and the name of each individual who provided the instruction.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-105. Records of surveys after source implant and removal. A licensee shall maintain a record of the surveys required by sections 33-10-07.1-48 (surveys after source implant and removal) and 33-10-07.1-60 (surveys of patients and human research subjects treated with a remote afterloader unit) for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-106. Records of brachytherapy source accountability.

1. A licensee shall maintain a record of brachytherapy source accountability required by section 33-10-07.1-49 (brachytherapy sources accountability) for three years.

2. For temporary implants, the record must include:

   a. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the

individual who removed them from storage, and the location of use; and

b. The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

3. For permanent implants, the record must include:

a. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

b. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

c. The number and activity of sources permanently implanted in the patient or human research subject.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-107. Records of calibration measurements of brachytherapy sources.

1. A licensee shall maintain a record of the calibrations of brachytherapy sources required by section 33-10-07.1-52 (calibration measurements of brachytherapy sources) for three years after the last use of the source.

2. The record must include:

a. The date of the calibration;

b. The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

c. The source output or activity;

d. The source positioning accuracy within the applicators; and

e. The signature of the authorized medical physicist.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-108. Records of decay of strontium-90 sources for ophthalmic treatments.

1. A licensee shall maintain a record of the activity of a strontium-90 source required by section 33-10-07.1-53 (decay of strontium-90 sources for ophthalmic treatments) for the life of the source.

2. The record must include:

   a. The date and initial activity of the source as determined under section 33-10-07.1-52 (calibration measurements of brachytherapy sources); and

   b. For each decay calculation, the date and the source activity as determined under section 33-10-07.1-53 (decay of strontium-90 sources for ophthalmic treatments).

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-109. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by section 33-10-07.1-61 (installation, maintenance, adjustment, and repair) for three years. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and the name of each individual who performed the work.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-110. Records of safety procedures. A licensee shall retain a copy of the procedures required by subdivision d of subsection 1 of section 33-10-07.1-62 (safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units) and subdivision b of subsection 4 of section 33-10-07.1-62 until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-111. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with section 33-10-07.1-64 (dosimetry equipment) for the duration of the license.

2. For each calibration, intercomparison, or comparison, the record must include:

   a. The date;

   b. The manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 1 and 2 of section 33-10-07.1-64 (dosimetry equipment);

   c. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

   d. The names of the individuals who performed the calibration, intercomparison, or comparison.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-112. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

1. A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by sections 33-10-07.1-65 (full calibration measurements on teletherapy units), 33-10-07.1-66 (full calibration measurements on remote afterloader units), and 33-10-07.1-67 (full calibration measurements on gamma stereotactic radiosurgery units) for three years.

2. The record must include:

   a. The date of the calibration;

   b. The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit;

   c. The results and an assessment of the full calibrations;

d. The results of the autoradiograph required for low dose-rate remote afterloader units; and

e. The signature of the authorized medical physicist who performed the full calibration.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-113. Records of periodic spot checks for teletherapy units.

1. A licensee shall retain a record of each periodic spot check for teletherapy units required by section 33-10-07.1-68 (periodic spot checks for teletherapy units) for three years.

2. The record must include:

   a. The date of the spot check;

   b. The manufacturer's name, model number, and serial number of the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

   c. An assessment of timer linearity and constancy;

   d. The calculated on-off error;

   e. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

   f. The determined accuracy of each distance measuring and localization device;

   g. The difference between the anticipated output and the measured output;

   h. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

   i. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

3. A licensee shall retain a copy of the procedures required by subsection 2 of section 33-10-07.1-68 (periodic spot checks for teletherapy units) until the licensee no longer possesses the teletherapy unit.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-114. Records of periodic spot checks for remote afterloader units.

1. A licensee shall retain a record of each spot check for remote afterloader units required by section 33-10-07.1-69 (periodic spot checks for remote afterloader units) for three years.

2. The record must include, as applicable:

   a. The date of the spot check;

   b. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

   c. An assessment of timer accuracy;

   d. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

   e. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

3. A licensee shall retain a copy of the procedures required by subsection 2 of section 33-10-07.1-69 (periodic spot checks for remote afterloader units) until the licensee no longer possesses the remote afterloader unit.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-115. Records of periodic spot checks for gamma stereotactic radiosurgery units.

1. A licensee shall retain a record of each spot check for gamma stereotactic radiosurgery units required by section 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units) for three years.

2. The record must include:

   a. The date of the spot check;

   b. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

   c. An assessment of timer linearity and accuracy;

   d. The calculated on-off error;

   e. A determination of trunnion centricity;

   f. The difference between the anticipated output and the measured output;

   g. An assessment of source output against computer calculations;

   h. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

   i. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

3. A licensee shall retain a copy of the procedures required by subsection 2 of section 33-10-07.1-70 (periodic spot checks for gamma stereotactic radiosurgery units) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-116. Records of additional technical requirements for mobile remote afterloader units.

1. A licensee shall retain a record of each spot check for mobile remote afterloader units required by section 33-10-07.1-71 (additional technical requirements for mobile remote afterloader units) for three years.

2. The record must include:

a. The date of the spot check;

b. The manufacturer's name, model number, and serial number of the remote afterloader unit;

c. Notations accounting for all sources before the licensee departs from a facility;

d. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

e. The signature of the individual who performed the spot check.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-117. Records of surveys of therapeutic treatment units.

1. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with section 33-10-07.1-72 (radiation surveys) for the duration of use of the unit.

2. The record must include:

   a. The date of the measurements;

   b. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

   c. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

   d. The signature of the individual who performed the test.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-118. Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

1. A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by

section 33-10-07.1-73 (five-year inspection for teletherapy and gamma stereotactic radiosurgery units) for the duration of use of the unit.

2. The record must contain:

   a. The inspector's radioactive materials license number;

   b. The date of inspection;

   c. The manufacturer's name and model number and serial number of both the treatment unit and source;

   d. A list of components inspected and serviced, and the type of service; and

   e. The signature of the inspector.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-119. Report and notification of a medical event.

1. A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

   a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than fifty millisieverts [5 rems] effective dose equivalent, five hundred millisieverts [50 rems] to an organ or tissue, or five hundred millisieverts [50 rems] shallow dose equivalent to the skin; and

      (1) The total dose delivered differs from the prescribed dose by twenty percent or more;

      (2) The total dosage delivered differs from the prescribed dosage by twenty percent or more or falls outside the prescribed dosage range; or

      (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty percent or more.

   b. A dose that exceeds fifty millisieverts [5 rems] effective dose equivalent, five hundred millisieverts [50 rems] to an organ or tissue, or five hundred millisieverts [50 rems] shallow dose equivalent to the skin from any of the following:

(1) An administration of a wrong radioactive drug containing radioactive material;

(2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(3) An administration of a dose or dosage to the wrong individual or human research subject;

(4) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(5) A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by five hundred millisieverts [50 rems] to an organ or tissue and fifty percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

2. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

3. The licensee shall notify the department by telephone no later than the next calendar day after discovery of the medical event.

4. The licensee shall submit a written report to the department within fifteen days after discovery of the medical event.

a. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on each individual who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

b. The report may not contain the individual's name or any other information that could lead to identification of the individual.

5. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

7. A licensee shall:

a. Annotate a copy of the report provided to the department with the:

(1) Name of the individual who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-120. Report and notification of a dose to an embryo, a fetus, or a nursing child.

1. A licensee shall report any dose to an embryo or a fetus that is greater than fifty millisieverts [5 rems] dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by the authorized user.

2. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

   a. Is greater than fifty millisieverts [5 rems] total effective dose equivalent; or

   b. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

3. The licensee shall notify the department by telephone no later than the next calendar day after discovery of a dose to the embryo or fetus or nursing child that requires a report in subsection 1 or 2.

4. The licensee shall submit a written report to the department within fifteen days after discovery of a dose to the embryo or fetus or nursing child that requires a report in subsection 1 or 2.

   a. The written report must include:

      (1) The licensee's name;

      (2) The name of the prescribing physician;

      (3) A brief description of the event;

      (4) Why the event occurred;

      (5) The effect, if any, on the embryo or fetus or the nursing child;

      (6) What actions, if any, have been taken or are planned to prevent recurrence; and

      (7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

   b. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

5. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty-four hours after discovery of an event that would require reporting under subsection 1 or 2, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty-four hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo or fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

6. A licensee shall:

   a. Annotate a copy of the report provided to the department with the:

      (1) Name of the pregnant individual or the nursing child who is the subject of the event; and

      (2) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

   b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than fifteen days after the discovery of the event.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07.1-121. Report of a leaking source. A licensee shall file a report within five days if a leak test required by section 33-10-07.1-29 (requirements for possession of sealed sources and brachytherapy sources) reveals the presence of one hundred eighty-five becquerels [.005 microcurie] or more of removable contamination. The report must be filed with the department. The written report must include the model number and serial number if assigned, of the leaking

source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-09

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, 33-10-04.1, 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~~ 33-10-07.1, or both. Registrants 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; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-10.1-04

CHAPTER 33-10-10

33-10-10-02. General regulatory provisions and specific requirements.

1. **Posting of notices to workers.**

   a. Each licensee or registrant shall post current copies of the following documents:

      (1) This chapter and chapter 33-10-04.1.

      (2) The license, certificate of registration, conditions, or documents incorporated into the license by reference and amendments thereto.

      (3) The operating procedures applicable to activities 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. The department's "Notice to Employees" form (SFN 8414) must be posted by each licensee or registrant as required by this article.

   d. Documents, notices, or forms posted pursuant to this subsection must 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, must be conspicuous, and must be replaced if defaced or altered.

   e. Department documents posted pursuant to paragraph 4 of subdivision a must be posted within five working days after receipt of the documents from the department. The licensee's or registrant's response, if any, must be posted within five working days after dispatch from the licensee or registrant. Such documents must 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.**

a. All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of one millisievert [100 millirem]:

(1) ~~Must be kept~~ Kept informed of the storage, transfer, or use of ~~sources of~~ radiation or radioactive material.

(2) ~~Must be instructed~~ Instructed in the health protection problems associated with exposure to radiation or radioactive material ~~to the individual and potential offspring~~, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.

(3) ~~Must be instructed~~ Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of this article and licenses for the protection of personnel from exposures to radiation or radioactive material.

(4) ~~Must be instructed~~ Instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of North Dakota Century Code chapter 23-20.1, this article, and licenses or unnecessary exposure to radiation or radioactive material.

(5) ~~Must be instructed~~ 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.

(6) ~~Must be advised~~ Advised as to the radiation exposure reports which workers ~~must be furnished~~ may request pursuant to subsection 3.

b. In determining those individuals subject to the requirements of subdivision a, licensees and registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

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 must be reported to the individual as specified in this subsection. The information

reported must include data and results obtained pursuant to this article, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to subsection 7 of section 33-10-04.1-15. Each notification and report must:

(1) Be in writing.

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number.

(3) Include the individual's exposure information.

(4) Contain the following statement:

This report is furnished to you under the provisions of North Dakota ~~State~~ Radiological Health Rules (North Dakota Administrative Code chapter 33-10-10). You should preserve this report for further reference.

b. Each licensee or registrant shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to subsection 7 of section 33-10-04.1-15.

c. Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to subsection 2 of section 33-10-04.1-09 or the monitoring requirements in effect prior to March 1, 1994. Such report must be furnished within thirty days from the date of the request, or within thirty days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report must cover the period of time that the worker's activities involved exposure to sources of radiation and must 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 section 33-10-04.1-16 to report to the department any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a copy of the report submitted to the department. Such reports must be transmitted at a time not later than the transmittal to the department.

e. At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

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 must be routinely engaged in work under control of the licensee or registrant and must 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, must 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 must be an individual previously authorized by the licensee or registrant to enter that area. With regard to areas containing information classified by an agency of the United States government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so.

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 rules 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, must comply with the requirements of subdivision a of subsection 6.

   c. The provisions of subdivision b may 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 believing that violations of North Dakota Century Code chapter 23-20.1, this article, or license conditions 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 must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of the workers. A copy must 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 may 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, an inspection must 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 ~~license~~ licensee, registrant, or contractor or subcontractor of a licensee or registrant may 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. (1) 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.

(2) 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 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 must be without prejudice to the filing of a new complaint meeting the requirements of subdivision a of subsection 6.

History: Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-11

33-10-11-01. Purpose. This chapter establishes fees charged for the issuance of licenses and registration certificates by the department. This chapter also establishes fees charged to recover costs associated with nonroutine regulatory inspections and surveys of licensees and registrants ~~based upon a prescribed schedule by licensee or registrant type~~.

History: Effective October 1, 1982; amended effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

33-10-11-04. Payment of fees. The following fees are nonrefundable:

1. **License and registration fees.** The appropriate licensing or registration fee shall accompany the application for licensure or registration when filed with the department. For radioactive material licenses, the application fee is equal to the appropriate annual fee.

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. For radioactive material licenses that are current on their annual fee payments, no renewal fee will be assessed.

4. **Reciprocity fee.** The appropriate reciprocity fee shall accompany the written notification as required in sections 33-10-03-06 and 33-10-02-11.

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. Special project fees will be based upon the current professional staff hourly rate (thirty-three percent of the current nuclear regulatory commission rate listed in 10 CFR 170.20).

6. **Annual fees.** Annual fees are required to be paid by all radioactive material licensees no later than January first of each year the license is active, except that the annual fee due on January first of the year following the issuance of a new license shall be prorated to the number of months the license was in effect the first calendar year (example: for a new license issued in May the annual fee due January first would be seven-twelfths [June-December] of the annual fee listed in appendix A).

7. **Inspection and survey fees.** Fees for regulatory inspections and surveys of North Dakota licensees are included in the registration or annual fees for each registration or license type. Nonroutine inspections will require the nonroutine inspection fee to be paid upon notification by the department when the inspection has been completed.

8. **Annual fees for small entities.** An industrial radiography or well logging licensee may qualify as a small entity. If a licensee qualifies as a small entity and provides the department with the proper certification, the maximum annual fee shall be one thousand ~~two~~ three hundred fifty dollars for industrial radiography or one thousand two hundred dollars for well logging. If the annual receipts of a small entity engaged in industrial radiography or well logging are below three hundred fifty thousand dollars, the annual fee is five hundred dollars.

   a. A licensee qualifies as a small entity if it meets the following size standards:

      (1) A small business is a business with annual receipts of three and one-half million dollars or less ~~except private practice physicians for which the standard is annual receipts of one million dollars or less~~.

      (2) A small organization is a not-for-profit organization which is independently owned and operated and has annual receipts of three and one-half million dollars or less.

      (3) Small governmental jurisdictions are governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than fifty thousand.

      (4) A small educational institution is one that is:

         (a) Supported by a qualifying small governmental jurisdiction; or

         (b) One that is not state or publicly supported and has five hundred employees or less.

      (5) A licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of this section.

   b. A licensee who seeks to establish status as a small entity for purposes of paying the fees required under this chapter shall file a certification statement with the department. The licensee shall:

      (1) Certify, on the business's letterhead, that the business meets the conditions in subdivision a of subsection 8 of this section;

(2) Sign the certification as the chief executive officer of the business or as an official designee; and

(3) Have the certification notarized.

c. A licensee who seeks to qualify as a small entity shall submit the certification with the reduced annual fee payment.

d. For purposes of this chapter, the licensee shall submit a new certification with its annual fee payment each year.

9. **Method of payment.** Fee payments shall be by check, draft, or money order made payable to the North Dakota ~~state~~ department of health ~~and consolidated laboratories~~.

10. **Submittal 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
Division of ~~Environmental Engineering~~ Air Quality
1200 Missouri Avenue, Room 304
Box 5520
Bismarck, ND 58506-5520

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

33-10-11-05. Failure by applicant or licensee to pay prescribed fees.

1. In any case where the department finds that an applicant or a licensee has failed to pay a prescribed fee required in this chapter, the department will not process any application and may suspend or revoke any license or approval involved or may issue an order with respect to licensed activities as the department determines to be appropriate or necessary in order to carry out the provisions of this chapter and of the North Dakota Century Code.

2. In any case where the department does not receive the prescribed fee by the stated due date, an additional fee shall be levied as stated in category 30 of appendix A.

History: Effective October 1, 1982; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

APPENDIX A
SCHEDULE OF FEES FOR RADIOACTIVE MATERIAL LICENSES

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the following fees.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Amendment Non-routine inspection Annual Fee	Full Cost Full Cost $82,100	Items 26 and/or 30 as applicable.
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Amendment Non-routine Inspection Annual Fee	N/A N/A N/A	N/A
C	Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including X-ray fluorescence analyzers.	Amendment Non-routine Inspection Annual Fee	$150 $500 $700	Items 26 and/or 30 as applicable.

D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Amendment Non-routine Inspection Annual Fee	$150 $500 $1,050	Items 26 and/or 30 as applicable.
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Amendment Non-routine Inspection Annual Fee	Full Cost Full Cost $426,900	Items 26 and/or 30 as applicable.
B	Licenses for possession, use and or installation of source material for shielding only.	Amendment Non-routine inspection Annual Fee	$50 $150 $250	Items 26 and/or 30 as applicable.
C	All other source material licenses.	Amendment Non-routine inspection Annual Fee	$170 $570 $1,750	Items 26 and/or 30 as applicable.

3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to Chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Amendment Non-routine inspection Annual Fee	$100 $1,200 $5,000	Items 26 and/or 30 as applicable.
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to Chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Amendment Non-routine inspection Annual Fee	$210 $750 $2,300	Items 26 and/or 30 as applicable.

C	Licenses issued pursuant to Chapter 33-10-03 authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generator, reagent kits and/or sources and devices containing byproduct material or naturally occurring or accelerator-produced radioactive material.	Amendment Non-routine inspection Annual Fee	$170 $720 $5,000	Items 26 and/or 30 as applicable.
D	License and approvals issued pursuant to Chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material	Amendment Non-routine inspection Annual Fee	$120 $450 $2,000	Items 26 and/or 30 as applicable.
E	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).	Amendment Non-routine inspection Annual Fee	$130 $260 $900	Items 26 and/or 30 as applicable.

F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Amendment Non-routine inspection Annual Fee	$130 $300 $870	Items 26 and/or 30 as applicable.
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Amendment Non-routine inspection Annual Fee	$175 $525 $8,000	Items 26 and/or 30 as applicable.

H	Licenses issued pursuant to Chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of Chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of Chapter 33-10-03.	Amendment Non-routine inspection Annual Fee	$100 $400 $2,600	Items 26 and/or 30 as applicable.

I	Licenses issued pursuant to Chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of Chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Chapter 33-10-03.	Amendment Non-routine inspection Annual Fee	$130 $260 $3,900	Items 26 and/or 30 as applicable.

J	Licenses issued pursuant to Chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require sealed source and/or device review to persons generally licensed under Chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Amendment Non-routine inspection Annual Fee	$150 $390 $2,400	Items 26 and/or 30 as applicable.

K	Licenses issued pursuant to Chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Amendment Non-routine inspection Annual Fee	$110 $390 $1,000	Items 26 and/or 30 as applicable.
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to Chapter 33-10-03 for research and development that do not authorize commercial distribution.	Amendment Non-routine inspection Annual Fee	$190 $450 $1,500	Items 26 and/or 30 as applicable.

M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to Chapter 33-10-03 for research and development that do not authorize commercial distribution.	Amendment Non-routine inspection Annual Fee	$240 $350 $1,400	Items 26 and/or 30 as applicable.
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Amendment Non-routine inspection Annual Fee	$150 $390 $2,260	Items 26 and/or 30 as applicable.
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to Chapter 33-10-05 for industrial radiographic operations.	Amendment Non-routine inspection Annual Fee (Standard) Annual Fee (Small Entity)	$190 $940 $3,050 $1,350	Items 26 and/or 30 as applicable.

P		All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Catergories 4A through 10D.	Amendment Non-routine inspection Annual Fee	$140 $680 $870	Items 26 and/or 30 as applicable.
	1	Fixed gas chromatographs and/or non-portable X-ray fluorescence analyzers only.	Amendment Non-routine inspection Annual Fee	$115 $300 $400	Items 26 and/or 30 as applicable. An additional $100 if possess 10 or more devices.
	2	Portable X-ray fluroescence analyzers only.	Amendment Non-routine inspection Annual Fee	$115 $350 $500	Items 26 and/or 30 as applicable. An additional $100 if possess 10 or more devices.
	3	Spinning pipe-thickness gauges only.	Amendment Non-routine inspection Annual Fee	$140 $600 $800	Item 30 as applicable. An additional $100 per extra licensed location and an additional $100 if possess more than 5 devices.
	4	Moisture and/or density measuring gauges only.	Amendment Non-routine inspection Annual Fee	$150 $500 $800	Item 30 as applicable. An additional $100 per extra licensed location and an additional $100 if possess 10 more gauges.
	5	All other portable and mobile gauging devices only.	Amendment Non-routine inspection Annual Fee	$150 $650 $800	Item 30 as applicable. An additional $100 per extra licensed location and an additional $100 if possess more than 10 or more gauges.

	6	Fixed level and/or density gauges only.	Amendment Non-routine inspection Annual Fee	$140 $500 $800	Items 30 as applicable. An additional $100 per extra licensed location and an additional $150 if possess 25 or more gauges.
Q		Registration of a device(s) generally licensed under Chapter 33-10-03. (Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)	Amendment Non-routine inspection Annual Registration	$100 $250 $450	Items 30 as applicable. An additional $150 if possess 25 or more devices
4. WASTE DISPOSAL AND PROCESSING					

A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material.	Amendment Non-routine inspection Annual Fee	Full Cost Full Cost $49,900	Items 26 and/or 30 as applicable.

B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	Amendment Non-routine inspection Annual Fee	$100 $790 $6,000	Items 26 and/or 30 as applicable.
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	Amendment Non-routine inspection Annual Fee	$100 $790 $2,800	Items 26 and/or 30 as applicable.
5. WELL LOGGING				

A	Licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies.	Amendment Non-routine inspection Annual Fee Standard Annual Fee (Small Entity)	Full Cost $380 $5,800 $4,000	Items 26 and/or 30 as applicable.
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Amendment Non-routine inspection Annual Fee Standard Annual Fee (Small Entity)	Full Cost $380 $5,800 $4,000	Items 26 and/or 30 as applicable.
6. NUCLEAR LAUNDRY				
	Licenses for commercial collection and laundry of items contaminated with byproduct material, naturally occurring or accelerator-produced radioactive material, source material or special nuclear material.	Amendment Non-routine inspection Annual Fee	$130 $720 $2,700	Items 26 and/or 30 as applicable.
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED, SOURCE, OR SPECIAL NUCLEAR MATERIAL				

A	Licenses issued pursuant to Chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in sealed sources contained in teletherapy devices.	Amendment Non-routine inspection Annual Fee	$160 $720 $6,200	Items 26 and/or 30 as applicable.
B	Licenses of broad scope issued to medical institutions or two or more physicians pursuant to Chapter 33-10-03 authorizing research and development, including human use of byproduct material, except licenses for byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in sealed sources contained in teletherapy devices.	Amendment Non-routine inspection Annual Fee	$140 $680 $6,500	Items 26 and/or 30 as applicable.

C	Other licenses issued pursuant to Chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Amendment Non-routine inspection Annual Fee	$160 $570 $2,200	Items 26 and/or 30 as applicable.

	1	Licenses issued pursuant to Chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material including the possession and use of computerized remote high dose-rate after loading brachytherapy (HDR) devices, and/or the use of radioactive material for positron emission tomography (PET).	Amendment Non-routine inspection Annual Fee	$150 $670 $2,500	Items 26 and/or 30 as applicable.
	2	Licenses issued pursuant to Chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material including the possession and use of sealed sources for brachytherapy (except HDR devices).	Amendment Non-routine inspection Annual Fee	$160 $560 $2,400	Items 26 and/or 30 as applicable.

	3	Licenses issued pursuant to Chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for nuclear medicine diagnostic procedures only.	Amendment Non-routine inspection Annual Fee	$140 $510 $2,100	Items 26 and/or 30 as applicable.
	4	Licenses issued pursuant to Chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for nuclear medicine procedures performed by a mobile nuclear medicine service.	Amendment Non-routine inspection Annual Fee	$160 $680 $2,200	Item 30 as applicable. An additional $200 per extra licensed location and an additional $100 if licensed for the use of radioactive material for positron emission tomography (PET).
8. VETERINARY MEDICINE					

A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Amendment Non-routine inspection Annual Fee	$140 $450 $1,300	Items 26 and/or 30 as applicable.
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Amendment Non-routine inspection Annual Fee	$140 $450 $1,500	Items 26 and/or 30 as applicable.
9. CIVIL DEFENSE				
	Licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Amendment Non-routine inspection Annual Fee	$120 $260 $700	Items 26 and/or 30 as applicable.
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION				

A	Safety evaluation of devices or products containing byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution.	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
B	Safety evaluation of devices or products containing byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by a single applicant, except reactor fuel devices.	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
C	Safety evaluation of sealed sources containing byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material, except reactor fuel, for commercial distribution.	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A

D	Safety evaluation of sealed sources containing byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by a single applicant, except reactor fuel.	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
11.	Transportation of radioactive material (Regulated by DOT and/or NRC).	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
12.	Review of standardized spent fuel facilities (Regulated by NRC).	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
13.	Special projects.	Amendment Non-routine inspection Annual Fee	Full Cost Full Cost Full Cost	Items 26 and/or 30 as applicable.
14. SPENT FUEL STORAGE				
A	Spent fuel storage cask Certificate of Compliance (Regulated by NRC).	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
B	Inspections related to spent fuel storage cask Certificate of Compliance (Regulated by NRC).	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
C	Inspections related to storage of spent fuel (Regulated by NRC).	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A

15.	Byproduct, naturally occurring or acccelerator-produced, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation or site restoration activities pursuant to 10 CFR Parts 30, 40, 70, and 72.	Amendment Non-routine inspection Annual Fee	Full Cost Full Cost Full Cost	Items 26 and/or 30 as applicable.
16.	Import and export licenses (Regulated by NRC).	Amendment Non-routine inspection Annual Fee	N/A N/A N/A	N/A
17.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of Chapters 33-10-02 and 33-10-03. (Application fee is due three working days prior to entering the state.)	Application Fee Non-routine Inspection	Same as annual fee for license type Same as inspection fee for license type	Items 26 and/or 30 as applicable.
18. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Amendment Non-routine inspectionv Annual Fee	$140 $350 $650	Items 26 and/or 30 as applicable.
B	Instrument calibration services (for other licensed entities) only.	Amendment Non-routine inspection Annual Fee	$140 $350 $650	Items 26 and/or 30 as applicable.
19.	Combination leak test and analysis services and instrument calibration services (for other licensed entities) only.	Amendment Non-routine inspection Annual Fee	$150 $400 $870	Items 26 and/or 30 as applicable.

20.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Amendment Non-routine inspection Annual Fee	$100 $250 $450	Items 26 and/or 30 as applicable.
21.	Storage of radioactive material only.	Amendment Non-routine inspection Annual Fee	$140 $350 $600	Items 30 as applicable. An additional $100 per extra licensed location and an additional $100 if possess 10 or more sources.
22. DECONTAMINATION SERVICES				
A	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a mobile unit only.	Amendment Non-routine inspection Annual Fee	$160 $500 $1,200	Items 26 and/or 30 as applicable.
B	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Amendment Non-routine inspection Annual Fee	$250 $650 $8,000	Items 26 and/or 30 as applicable.

23.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$200	Item 30 as applicable.
24.	Demonstration and sales of devices containing radioactive materials	Annual Fee	$200	Item 30 as applicable.
25.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$760	Item 30 as applicable.
26.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6. or 21 above.)	Annual Fee	25% of Base Fee for Category Type per Location	Item 30 as applicable.
27.	Administrative amendment (limited to the following amendments only):	Amendment	$100	Item 30 as applicable.
	- Corporate name change with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manual changes (industrial users only) - Filing of training certificates (gauge users only)			

28.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full Cost	Item 30 as applicable.
29.	Certificate - in vitro testing with radioactive material under general license.	Certificate Fee (Valid for three years)	$120	Item 30 as applicable.
30.	Late payment of any fees described in items 1-29 above.	From payment due date	Fee Amount	An additional $30 per 30 days late.

Note: All fee amounts are shown in United States dollars (USD).

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04.5, 28-32-02
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

APPENDIX B
SCHEDULE OF FEES FOR REGISTRATION CERTIFICATION AND INSPECTIONS

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	95
Medical:	
A. Radiographic Machine (including computed tomography)	150
B. Fluoroscopic Machine	230
C. Combined Radiographic-Fluoroscopic	300
D. (1) Therapeutic: Linear Acccelerator (Less than 10MEV)	230
(2) Therapeutic: Linear Accelerator (greater than 10MEV)	375
E. Superficial X-ray	115
Chiropractic	140
Podiatry	115
Veterinary Medicine	95
Industrial Radiography	375
Accelerators (Industrial and Research)	230
Education and Research	230

Other Registration Fees and Services	Annual Service Fees (in dollars)
X-ray Service and Installers	230
Radiation Training Courses	150
X-ray Sales and Demonstrations	230
Combined Sales and Service (Assembler)	300
Dosimeterists and Physicists	150
Shielding Evaluations (Routine)	230 per evaluation

Shielding Evaluations (Nonroutine)	Full cost
Reciprocity (X-ray producing machines)	230 per year per machine

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; March 1, 2003.
General Authority: NDCC 23-20.1-04.5, 28-32-02
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

CHAPTER 33-10-12

33-10-12-01. Purpose. This chapter establishes radiation safety requirements for persons using sources of radiation for wireline service operations including well logging, mineral logging, radioactive tracers, radioactive markers, and ~~subsurface tracer studies~~ uranium sinker bars. The requirements of this chapter are in addition to, and not in substitution for, ~~the~~ other requirements of chapters 33-10-01, ~~33-10-02,~~ 33-10-03, 33-10-04.1, ~~and~~ 33-10-10, 33-10-11, and 33-10-13.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-12-02. Scope. This chapter applies to all licensees or registrants who use sources of radiation for wireline service operations including well logging, mineral logging, radioactive tracers, radioactive markers, or ~~subsurface tracer studies~~ uranium sinker bars. The requirements set out in this chapter do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or the use of sealed sources auxiliary to well logging but not lowered into wells.

History: Effective June 1, 1986; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-12-03. Definitions. As used in this chapter, the following definitions apply:

1. "Energy compensation source (ECS)" means a small sealed source, with an activity not exceeding three and seven-tenths megabecquerels [100 microcuries], used within a logging tool or other tool components to provide a reference standard to maintain the tool's calibration when in use.

2. "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

3. "Fresh water aquifer" means a geologic formation that is capable of yielding fresh water to a well or spring.

~~2.~~ 4. "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

~~3.~~ 5. "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by subsection 1 of section 33-10-12-08.

~~4.~~ 6. "Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at ~~the well site~~ a temporary jobsite and who is responsible to the licensee for assuring compliance with department requirements and conditions of the license.

~~5.~~ 7. "Logging tool" means a device used subsurface to perform well logging.

~~6.~~ 8. "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

~~7.~~ 9. "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.

~~8.~~ 10. "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation. This term includes radioactive collar markers and radioactive iron nails.

11. "Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask questions.

~~9.~~ 12. "Source holder" means a housing or assembly into which a radioactive source is placed ~~for the purpose of facilitating~~ to facilitate the handling and use of the source in well logging operations.

~~10.~~ 13. "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.

14. "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in the well to isolate fresh water aquifers from the well.

~~11.~~ 15. "Temporary jobsite" means a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

16. "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

~~12.~~ 17. "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool ~~down~~ toward the bottom of a well.

~~13.~~ 18. "Well" or "well bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

~~14.~~ 19. "Well logging" means all operations involving the 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 or adjacent formations.

~~15.~~ 20. "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well bore.

~~16.~~ 21. "Wireline service operation" means any evaluation or mechanical service which is performed in the well bore using devices on a wireline.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-12-04. Prohibition. ~~No licensee may perform wireline 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~~ A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

1. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made~~; and~~.

2. In the event a decision is made to abandon the sealed source downhole, the requirements of subsection 3 of section 33-10-12-09 shall be met.

3. The required radiation monitoring will be performed.

4. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.

5. If the environment, any equipment, or personnel are contaminated with licensed material, they shall be decontaminated before release from the site or released for unrestricted use.

6. The licensee shall retain a copy of the written agreement for three years after the completion of the well logging operation.

7. The licensee may apply for department approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized by this chapter.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04, 23-20.1-08

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 33-10-13 and the dose limitation requirements of chapter 33-10-04.1 are met.

2. **Storage precautions.**

   a. Each source of radiation, except accelerators, must be provided with a storage or transport container. The container 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 section 33-10-04.1-09. Instrumentation shall be capable of measuring ~~twenty-five and eight-tenths nanocoulombs per kilogram [0.1 milliroentgen]~~ one microsievert [0.1 millirem] per hour through at least ~~twelve and nine-tenths microcoulombs per kilogram [50 milliroentgens]~~ five hundred microsievert [50 millirem] per hour. ~~Survey instruments acquired before March 1,1992, and capable of measuring twenty-five and eight-tenths nanocoulombs per kilogram [0.1 milliroentgen] per hour through at least five and sixteen hundredths microcoulombs per kilogram [20 milliroentgens] per hour also satisfy this requirement until March 1, 1997.~~

   b. Each radiation survey instrument shall be calibrated:

(1) At intervals not to exceed six months and after each instrument servicing except battery replacement;

(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(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 three 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 becquerels [microcuries] and maintained for inspection by the department for three years from the date the leak test is performed.

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 one hundred eighty-five becquerels [0.005 microcurie] of radioactive material on the test sample.~~ The wipe of a sealed source shall be performed using a leak test kit or method approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of one hundred eighty-five becquerels [0.005 microcurie] of radioactive material on the test sample and must be performed by a person approved by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to perform the analysis.

c. Interval of testing.

(1) Each sealed source of radioactive material, except an energy compensation source (ECS), 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.

(2) Each energy compensation source that is not exempt from testing in accordance with subdivision e must be tested at intervals not to exceed three years. In the absence of a certificate from the transferor indicating that a test has been made within the last three years before the transfer, the energy compensation source may not be used until tested.

d. Leaking or contaminated sources. If the test reveals the presence of one hundred eighty-five becquerels [0.005 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 within five days of receiving the test results.

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 (tritium) 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~~ beta-emitting or gamma-emitting, or both, radioactive material with an activity of three and seven-tenths megabecquerels [100 microcuries] or less.

(5) Sources of alpha-emitting or neutron-emitting, or both, radioactive material with an activity of three hundred seventy kilobecquerels [10 microcuries] or less.

6. **~~Quarterly~~ Physical inventory.** Each licensee or registrant shall conduct a ~~quarterly~~ semiannual physical inventory to account for all sources of radiation. Records ~~or~~ of inventories shall be maintained for three 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. Physical inventory records may be combined with leak test records.

7. **Utilization records.** Each licensee or registrant shall maintain current records, which shall be maintained for inspection by the department for three 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, and the disposition of any unused tracer material.

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 N43.6, "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126) in effect on June 1, 1986.~~

a. A licensee may use a sealed source for use in well logging applications if:

(1) The sealed source is doubly encapsulated;

(2) The sealed source contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) Meets the requirements of subdivision b, c, or d of this subsection.

b. For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources", or the requirements in subdivision c or d of this subsection.

c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification".

d. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if:

(1) The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(a) Temperature. The test source must be held at minus forty degrees Celsius for twenty minutes, six hundred degrees Celsius for one hour, and then be subject to a thermal shock test with a temperature drop from six hundred degrees Celsius to twenty degrees Celsius within fifteen seconds.

(b) Impact test. A five kilogram steel hammer, two and five-tenths centimeter in diameter, must be dropped from a height of one meter onto the test source.

(c) Vibration test. The test source must be subject to a vibration from twenty-five hertz to five hundred hertz at five times the acceleration of gravity for thirty minutes.

(d) Puncture test. A one gram hammer and pin, three-tenths centimeter pin diameter, must be dropped from a height of one meter onto the test source.

(e) Pressure tests. The test source must be subject to an external pressure of 1.695×10^{7} pascals [24600 pounds per square inch absolute].

e. The requirements in subdivision a, b, c, or d of this subsection do not apply to sealed sources that contain licensed material in gaseous form.

f. The requirements in subdivision a, b, c, or d of this subsection do not apply to energy compensation sources (ECS). These must be registered with the department under chapter 33-10-03 or with the United States nuclear regulatory commission or another agreement state.

~~d.~~ g. Certification documents shall be maintained for inspection by the department for a period of three 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~~ CAUTION* RADIOACTIVE MATERIAL

This labeling shall be on the smallest component transported as a separate piece of equipment.

b. Each transport and storage 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~~ CAUTION* RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

* or ~~CAUTION~~ DANGER

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

10. **Inspection and maintenance.**

a. Each licensee shall visually check source holders, logging tools, and source handling tools for defects before each use to ensure that the equipment is in good working condition and that the required labeling is present.

b. 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, uranium sinker bars, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of three years for inspection by the department.

~~b.~~ c. If any inspection conducted pursuant to subdivision a or b of this subsection reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made. A record must be made listing the date of check, name of inspector, equipment involved, defects found, and repairs made. These records must be maintained for three years after the defect is found.

~~c.~~ d. If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the United States nuclear regulatory commission, an agreement state, or a licensing state to perform this operation.

~~d.~~ e. 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.

11. **Subsurface tracer studies.**

a. The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license,

other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

b. A licensee shall not knowingly inject licensed material into fresh water aquifers unless specifically authorized by the department.

12. **Radioactive markers.** The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in schedule B of chapter 33-10-03. The use of markers is subject only to the requirements of subsection 5.

13. **Uranium sinker bars.** The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words, "CAUTION: RADIOACTIVE - DEPLETED URANIUM", and, "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

14. **Use of a sealed source in a well without a surface casing.** The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the department, the United States nuclear regulatory commission, or another agreement state.

15. **Energy compensation source.** The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the energy compensation source contains quantities of licensed material not exceeding three and seven-tenths megabecquerels [100 microcuries].

a. For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of subsections 5, 6, and 7 of section 33-10-12-05.

b. For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of section 33-10-12-04; subsections 5, 6, 7, and 14 of section 33-10-12-05; and section 33-10-12-09.

16. **Tritium neutron generator target source.**

a. Use of a tritium neutron generator target source, containing quantities not exceeding one thousand one hundred ten megabecquerels [30 curies] and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this chapter except section 33-10-12-04, subsection 8 and section 33-10-12-09.

b. Use of a tritium neutron generator target source, containing quantities exceeding one thousand one hundred ten megabecquerels [30 curies] or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this chapter except subsection 8.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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 as defined in this chapter 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 by successfully completing a written test.

      (2) Read and received instruction in the rules contained in this chapter and the applicable sections of chapters 33-10-01, 33-10-04.1, 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 by successfully completing a written test.

      (3) ~~Demonstrated~~ Has completed on-the-job training and demonstrated competence ~~to~~ in the use of sources of radiation, related handling tools, and radiation survey instruments ~~which will be used on the job~~ by a field evaluation.

   b. No licensee or registrant may permit any individual to act as a logging assistant or to assist in the handling of sources of radiation until such individual has:

      (1) Received instruction in applicable rules of this chapter and applicable sections of chapters 33-10-01, 33-10-04.1, and 33-10-10 or their equivalent and demonstrated an understanding thereof by successfully completing a written or oral test.

(2) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof by successfully completing a written or oral test.

~~(2)~~ (3) 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 provide safety reviews for logging supervisors and logging assistance at least once during each calendar year.

d. The licensee or registrant shall maintain employee training records for inspection by the department for three years following termination of employment. Records of annual safety reviews must list the topics discussed and also be retained for three years.

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, including the use of sealed sources in wells without surface casing for protecting fresh water aquifers if appropriate to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in chapter 33-10-04.1.

b. Methods and occasions for conducting radiation surveys, including surveys for decontamination, as required by section 33-10-12-08.

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 physically securing sources of radiation in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal.

f. Minimizing exposure of individuals in the event of an accident or from inhalation and ingestion of tracer materials.

g. Procedure for notifying proper personnel in the event of an accident.

h. Maintenance of records.

i. Inspection and maintenance of sealed sources, source holders, logging tools, source handling tools, storage containers, transport containers, ~~and~~ injection tools, and uranium sinker bars.

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.

l. For the use of tracers, decontamination of the environment, equipment, and personnel.

m. Maintenance of records generated by logging personnel at temporary jobsites.

n. Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by subsection 4 of section 33-10-12-05.

o. Use of remote handling tools for handling sealed sources and tracer material except low-activity calibration sources.

3. **Personnel monitoring.**

a. ~~No~~ The licensee or registrant may permit any individual to act as a logging supervisor or logging assistant 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~~, at all times during the handling of licensed radioactive materials, a personnel dosimeter that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and ~~thermoluminescent~~ other personnel dosimeters replaced at least quarterly. After replacement, each ~~film badge or thermoluminescent~~ personnel dosimeter must be promptly processed.

b. ~~Personnel~~ The licensee shall provide bioassay services to individuals using radioactive material in subsurface tracer studies if required by the license.

c. The licensee or registrant shall retain personnel monitoring records ~~shall be maintained~~ and bioassay results for inspection until the department authorizes disposition of the records.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-12-07. Precautionary procedures in logging and subsurface tracer operations.

1. **Security.**

   a. A logging supervisor must be physically present at a temporary jobsite whenever radioactive material is being handled or is not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

   b. During each logging or tracer application, except when the radiation sources are below ground or in secure shipping or storage containers, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in chapter 33-10-01.

2. **Handling tools.** The licensee shall provide and require the use of tools that will assure remote handling of sealed sources and tracer material other than low activity calibration sources.

3. ~~**Subsurface tracer studies.**~~

   ~~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.~~ **Particle accelerators.** 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, 7, and 8 of section 33-10-04.1-06 and section 33-10-04.1-07, as applicable, are met.

4. **Radioactive contamination control.**

a. If the licensee detects evidence that a sealed source has ruptured or radioactive material has caused contamination, the licensee shall initiate the emergency procedures required by subsection 2 of section 33-10-12-06.

b. If contamination results from the use of radioactive material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.

c. During efforts to recover a sealed source lodged in a well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-12-08. Radiation surveys and records.

1. **Radiation surveys.**

a. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used or stored.

b. Radiation surveys 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 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. If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

e. 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.~~ f. Records required pursuant to subdivisions a, b, c, d, and ~~d~~ e 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 three 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 documents.

   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~~ Physical inventories required pursuant to subsection 6 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.

   j. Training records required pursuant to subsection 1 of section 33-10-12-06.

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 the 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.

e. Shipping papers for the transportation of radioactive material.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

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

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

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

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

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

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

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

(2) ~~The setting of a whipstock or other deflection device~~ A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations.

(3) ~~The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by subsection 4~~ A permanent identification plaque, constructed of long-lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least seventeen centimeters (7 inches) square and three millimeters (1/8-inch thick). The plaque must contain the information required by subsection 4.

b. Notify the department by telephone~~, facsimile, or overnight express mail giving~~ of the circumstances of the loss~~,~~ and ~~request~~:

(1) Request approval of the proposed abandonment procedures~~.~~; or

(2) State that the licensee implemented abandonment before receiving department approval because the licensee believed there was an immediate threat to public health and safety.

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

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

The report must contain the following information:

(1) Date of occurrence.

(2) A description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form.

(3) Surface location and identification of well.

(4) Results of efforts to immobilize and set the source in place.

(5) A brief description of the attempted recovery effort.

(6) Depth of the radioactive source.

(7) Depth of the top of the cement plug.

(8) Depth of the well.

(9) The immediate threat to public health and safety justification for implementing abandonment prior to obtaining approval from the department.

(10) Any other information, such as a warning statement, contained on the permanent identification plaque.

~~(10)~~ (11) The names of the state agencies receiving a copy of this report.

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~~ as described in paragraph 3 of subdivision a of subsection 3.

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~~ number or other designation.

(6) The sealed sources by radionuclide and 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~~ this well", followed by the words, "before contacting the North Dakota 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 in proximity to an underground potable acquifer. 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; amended effective June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

APPENDIX A
SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

I. Fundamentals of radiation safety.

A. Characteristics of radiation.

B. Units of radiation dose and quantity of radioactivity.

C. Significance of radiation dose.

1. Radiation protection standards.

2. Biological effects of radiation dose.

D. Levels of radiation from licensed material.

E. Methods of minimizing radiation dose.

1. Working time.

2. Working distance.

3. Shielding.

F. Radiation safety practices including prevention of contamination and methods of decontamination.

II. Radiation detection instrumentation to be used.

A. Use of radiation survey instruments.

1. Operation.

2. Calibration.

3. Limitations.

B. Survey techniques.

C. Use of personnel monitoring equipment.

III. Equipment to be used.

A. Handling equipment.

B. Sources of radiation.

C. Storage and control of equipment.

D. Operation and control of equipment.

E. Maintenance of equipment.

IV. Storage, control, and disposal of licensed material.

V. The requirements of pertinent federal regulations and this article.

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

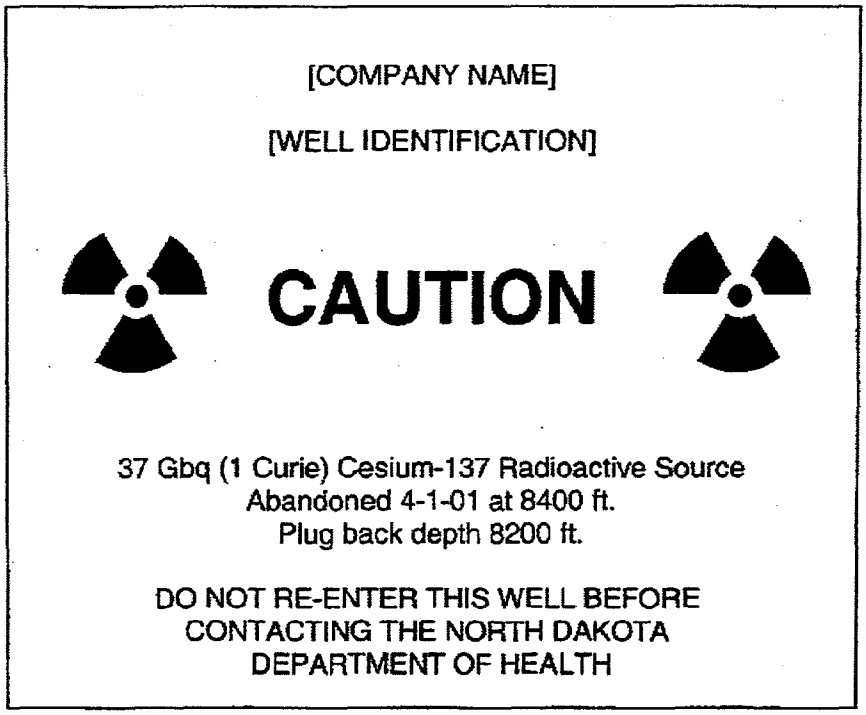
VII. The licensee's or registrant's recordkeeping procedures.

VIII. Case histories of accidents in well logging.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 2003.

APPENDIX B

Example of plaque for identifying wells containing sealed sources of radioactive material abandoned downhole.



The size of the plaque should be convenient for use on active or inactive wells, e.g., a 17-centimeter (7 inch) square. Letter size or the word "CAUTION" should be approximately twice the size of the rest of the information.

History: Effective June 1, 1986; amended effective June 1, 1992.

CHAPTER 33-10-13

33-10-13-01. Purpose and scope. The rules in this chapter establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport. To ensure compatibility with international transportation standards, all limits in this chapter are given in terms of dual units: The international system of units (SI) followed by United States customary units. The United States customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. ~~For the purpose of this chapter, either unit may be used.~~

History: Effective June 1, 1992; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-13-02. Definitions. As used in this chapter, the following definitions apply:

1. "Carrier" means any person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

2. "Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the United States nuclear regulatory commission.

3. "Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

4. "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized individuals to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but must limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

5. "Containment system" means the assembly of components of the packaging intended to retain the radioactive material during transport.

6. "Conveyance" means:

   a. For transport by public highway or rail: any transport vehicle or large freight container;

   b. For transport by water: any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

c. For transport by aircraft: any aircraft.

7. "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The ~~cosigner~~ consignor must issue specific instructions, in writing, for maintenance or exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the ~~cosigner~~ consignor.

8. "Fissile material" means any plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Department jurisdiction extends only to special nuclear material if quantities are not sufficient to form a critical mass as defined in chapter 33-10-01 of this article.

9. "Fissile material package" means a fissile material packaging together with its fissile material contents.

10. "Low specific activity (LSA) material" means radioactive material with limited specific activity that satisfies the descriptions and limits set forth below. Shielding materials surrounding the low specific activity material may not be considered in determining the estimated average specific activity of the package contents. Low specific activity material must be in one of three groups:

    a. Low specific activity-I (LSA-I).

        (1) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or

        (2) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

        (3) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

        (4) Mill tailings, contaminated earth, concrete, rubble, other debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average

specific activity does not exceed one millionth of the A_2 per gram.

b. Low specific activity-II (LSA-II).

(1) Water with tritium concentration up to eight-tenths of a terabecquerel per liter [20.0 curies/liter]; or

(2) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed one ten thousandths of an A_2 per gram for solids and gases, and one hundred thousandths of an A_2 per gram for liquids.

c. Low specific activity-III (LSA-III). Solids (e.g., consolidated wastes, activated materials) in which:

(1) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent, such as concrete, bitumen, ceramic, etc.;

(2) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed one-tenth of an A_2; and

(3) The average specific activity of the solid does not exceed two thousandths of an A_2 per gram.

11. "Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

12. "Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as special form radioactive material.

13. "Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

14. "Rules of the United States department of transportation" means the regulations in 49 CFR parts 100-189.

15. "Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

16. "Transport index" means the dimensionless number, rounded up to the first decimal place, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

    a. For nonfissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter [3.3 feet] from the external surface of the package by one hundred (equivalent to the maximum radiation level in millirem per hour at one meter [3.3 feet]); or

    b. For fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour at one meter [3.3 feet] from the external surface of the package by one hundred (equivalent to the maximum radiation level in millirem per hour at one meter [3.3 feet]), or, for criticality control purposes, the number obtained as described in 10 CFR 71.59, whichever is larger.

17. "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in appendix A of this chapter or may be determined by procedures described in appendix A of this chapter.

18. "Type B package" means a Type B packaging together with its radioactive contents. A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in section 33-10-13-08.

19. "Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR part 71.

20. "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

History: Effective June 1, 1992; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-13-04. Exemptions for low-level materials.

1. Common and contract carriers, freight forwarders, and warehousemen which are subject to the requirements 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), and the United States postal service are exempt from the requirements of this chapter to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the United States department of transportation or United States postal service are subject to section 33-10-13-03 and other applicable requirements of this article.

2. ~~Any~~ A licensee is exempt from the requirements of this chapter with respect to shipment or carriage of a package containing radioactive material having a specific activity not greater than seventy becquerels per gram [0.002 microcurie per gram].

~~3. With the exception of sections 33-10-13-05 and 33-10-13-16, a licensee is exempt from all requirements of this chapter, with respect to shipment or carriage of the following packages provided the packages contain no fissile material or meet the fissile material exemption standards in 10 CFR 71.53;~~

~~a. A package containing no more than a Type A quantity of radioactive material;~~

~~b. Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed seven hundred forty gigabecquerels [20 curies];~~

~~c. A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCOs), provided the external radiation level at three meters from the unshielded material or objects does not exceed ten millisieverts per hour [1 rem/hour]; or~~

~~d. A licensee is exempt from all requirements of this part, other than sections 33-10-13-05 and 33-10-13-16, with respect to shipment~~

~~or carriage of low specific activity (LSA) material in group LSA-I, or surface contaminated objects (SCOs) in group SCO-I.~~

History: Effective June 1, 1992; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-05. Transportation of licensed material.

1. Each licensee who transports licensed material outside ~~of the confines of the licensee's plant or other place of use~~ the site of usage, as specified in the department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall~~:~~

   ~~a.~~ ~~Comply~~ comply with the applicable requirements~~, appropriate to the mode of transport, of the regulations~~ of the United States department of transportation~~; and~~ regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.

   ~~(1)~~ a. The licensee shall particularly note United States department of transportation regulations in the following areas:

      ~~(a)~~ (1) Packaging--49 CFR part 173: subparts A and B and I.

      ~~(b)~~ (2) Marking and labeling--49 CFR part 172: ~~subparts~~ subpart D, sections 172.400 through 172.407, sections 172.436 through 172.440, and subpart E.

      ~~(c)~~ (3) Placarding--49 CFR part 172: subpart F, especially sections 172.500 through 172.519, 172.556, and appendices B and C.

      ~~(d)~~ (4) Accident reporting--49 CFR part 171: sections 171.15 and 171.16.

      ~~(e)~~ (5) Shipping papers and emergency information--49 CFR part 172: subparts C and G.

      ~~(f)~~ (6) Hazardous material employee training--49 CFR part 172: subpart H.

      ~~(g)~~ (7) Hazardous material shipper/carrier registration--49 CFR part 107: subpart G.

      ~~(h) Radiation protection program--49 CFR part 172: subpart I.~~

~~(2)~~ b. The licensee shall also note United States department of transportation regulations pertaining to the following modes of transportation:

~~(a)~~ (1) Rail--49 CFR part 174: subparts A through D and K.

~~(b)~~ (2) Air--49 CFR part 175.

~~(c)~~ (3) Vessel--49 CFR part 176: subparts A through F and M.

~~(d)~~ (4) Public highway--49 CFR part 177 and parts 390 through 397.

~~b. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.~~

2. If~~, for any reason, the regulations of the~~ United States department of transportation regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of ~~those regulations~~ the United States department of transportation specified in subsection 1 to the same extent as if the shipment ~~was~~ or transportation were subject to ~~the~~ United States department of transportation regulations.

History: Effective June 1, 1992; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-06. General licenses for carriers.

1. A general license is hereby issued to any common or contract carrier not exempt under section 33-10-13-04 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the United States department of transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those United States department of transportation requirements must be filed with, or made to, the department.

2. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the United States department of transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those United States department of transportation requirements must be filed with, or made to, the department.

3. Individuals who transport radioactive material pursuant to the general licenses in subsection 1 or 2 are exempt from the requirements of chapters ~~33-10-04~~ 33-10-04.1 and 33-10-10 to the extent that they transport radioactive material.

History: Effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-15. Routine determinations. Prior to each shipment of licensed material, the licensee shall determine that:

1. The package is proper for the contents to be shipped;

2. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

3. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

4. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

5. Any pressure relief device is operable and set in accordance with written procedures;

6. The package has been loaded and closed in accordance with written procedures;

7. Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by the United States nuclear regulatory commission;

8. The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in 49 CFR 173.443;

9. ~~External~~ Except as provided in subsection 10, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation, the radiation ~~levels around the package and around the vehicle, if applicable, will~~ level does not exceed two millisieverts per hour [200 millirems per hour] at any point on the external surface of the package ~~at any time during transportation. The~~, and the transport index ~~may~~ does not exceed ten;

10. ~~For a package transported in exclusive use by rail, highway, or water, radiation levels external to the package may exceed the limits specified~~

~~in subsection 9 but may not exceed any of the following~~ A package that exceeds the radiation level limits specified in subsection 9 must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

a. Two millisieverts per hour [200 millirems per hour] on the ~~accessible~~ external surface of the package, unless the following conditions are met, in which case the limit is ten millisieverts per hour [1000 ~~millirems~~ millirem per hour]~~:~~:

   (1) The shipment is made in a closed transport vehicle;

   (2) ~~Provisions are made to secure the~~ The package is secured within the vehicle so that its position ~~within the vehicle~~ remains fixed during transportation; and

   (3) There are no loading or unloading operations between the beginning and end of the transportation;

b. Two millisieverts per hour [200 ~~millirems~~ millirem per hour] at any point on the outer surface of the vehicle, including the ~~upper and lower surfaces,~~ top and underside of the vehicle; or, in the case of a ~~flatbed~~ flat-bed style vehicle, ~~with a personnel barrier~~ at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load ~~(~~or enclosure, if used~~)~~ and on the lower external surface of the vehicle~~. If no personnel barrier, the package cannot exceed 2 millisieverts per hour [200 millirems per hour] at the surface~~;

c. One-tenth millisievert per hour [10 millirems per hour] at any point two meters from ~~the vertical planes represented by~~ the outer lateral surfaces of the vehicle~~,~~ (excluding the top and underside of the vehicle); or, in the case of a ~~flatbed~~ flat-bed style vehicle, at any point two meters from the vertical planes projected ~~from~~ by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

d. Two hundredths millisieverts per hour [2 millirems per hour] in any normally occupied ~~positions of the vehicle~~ space, except that this provision does not apply to private ~~motor~~ carriers ~~when individuals occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with subsection 2 of section 33-10-10-02;~~ if exposed personnel under their control wear radiation dosimetry devices in conformance with subsection 2 of section 33-10-04.1-09.

11. For shipments made under the provisions of subsection 10, the shipper shall provide specific written instructions to the carrier for maintenance

of the exclusive use shipment controls. The instructions must be included with the shipping paper information;

12. The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public; and

13. A package must be prepared for transport so that in still air at thirty-eight degrees Celsius [100 degrees Fahrenheit] and in the shade, no accessible surface of a package would have a temperature exceeding fifty degrees Celsius [122 degrees Fahrenheit] in a nonexclusive use shipment or eighty-two degrees Celsius [180 degrees Fahrenheit] in an exclusive use shipment. Accessible package surface temperatures may not exceed these limits at any time during transportation.

History: Effective June 1, 1992; amended effective July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-19. Advance notification of ~~transport~~ shipment of irradiated reactor fuel and nuclear waste.

~~1. Prior to the transport of any irradiated reactor fuel or 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 irradiated reactor fuel or 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 irradiated reactor fuel or nuclear waste will be transported. A list of the mailing addresses of the governors and governors' designees is available upon request from the director, office of state programs, office of governmental and public affairs, United States nuclear regulatory commission, Washington, D.C. 20555-0001.~~

~~2. Advance notification is required only when:~~

~~a. The irradiated reactor fuel or nuclear waste is required to be in Type B packaging for transportation;~~

~~b. The irradiated reactor fuel or nuclear waste is being transported to, through, or across state boundaries to a disposal site or to a collection point for transport to a disposal site; and~~

~~c. The quantity of licensed material in a single package exceeds any of the following:~~

(1) Three thousand times the A_1 value of the radionuclides as specified in appendix A, for special form radioactive material;

(2) Three thousand times the A_2 value of the radionuclides as specified in appendix A, for normal form radioactive material; or

(3) One thousand terabecquerels [27000 curie].

3. Procedures for submitting advance notification.

a. The notification must be made in writing to the office of each appropriate governor or governor's designee and to the department.

b. 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.

c. A notification delivered by messenger must reach the office of the governor or of the 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.

d. The licensee shall retain a copy of the notification as a record for three years.

4. Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

a. The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

b. A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in 49 CFR 172.202 and 172.203(d);

c. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

d. The seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

e. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

~~f. A point of contact, with a telephone number, for current shipment information.~~

~~5. Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the state or of the governor's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.~~

~~6. Cancellation notice.~~

~~a. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified.~~

~~b. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.~~

1. As specified in subsections 2, 3, and 4, each licensee shall provide advance notification to the governor of a state, or the governor's designee, of the shipment of licensed material through, or across the boundary of the state, before the transport, or delivery to a carrier, for transport of licensed material outside the confines of the licensee's plant or other place of use or storage.

2. Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

   a. The licensed material is required by this chapter to be in type B packaging for transportation;

   b. The licensed material is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

   c. The quantity of licensed material in a single package exceeds the least of the following:

      (1) Three thousand times the A_1 value of the radionuclides as specified in appendix A, for special form radioactive material;

(2) Three thousand times the A_2 value of the radionuclides as specified in appendix A, for normal form radioactive material; or

(3) One thousand terabecquerels [27000 curies].

3. Procedures for submitting advance notification.

a. The notification must be made in writing to the office of each appropriate governor or governor's designee and to the administrator of the appropriate United States nuclear regulatory commission regional office listed in appendix A to 10 CFR part 73.

b. 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.

c. A notification delivered by messenger must reach the office of the governor or of the 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.

(1) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the federal register on June 30, 1995 [60 FR 34306].

(2) The list will be published annually in the federal register on or about June 30 to reflect any changes in information.

(3) A list of the names and mailing addresses of the governors' designees is available on request from the director, office of state programs, United States nuclear regulatory commission, Washington, D.C. 20555-0001.

d. The licensee shall retain a copy of the notification as a record for three years.

4. Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

a. The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

b. A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of the

United States department of transportation in 49 CFR 172.202 and 172.203(d);

c. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

d. The seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

e. The destination of the shipment and the seven-day period during which arrival of the shipment is estimated to occur; and

f. A point of contact, with a telephone number, for current shipment information.

5. Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with this section, will not be met shall telephone a responsible individual in the office of the governor of the state or of the governor's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

6. Cancellation notice.

a. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified, and to the administrator of the appropriate United States nuclear regulatory commission regional office listed in appendix A of 10 CFR part 73.

b. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.

History: Effective June 1, 1992; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-21. Completeness and accuracy of information.

1. Information provided to the department by an applicant for a license, or by a licensee, or information required by statute or by article 33-10, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

2. Each applicant or licensee shall notify the department of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this requirement only if the applicant or licensee fails to notify the department of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the department within two working days of identifying the information. This requirement is not applicable to information that is already required to be provided to the department by other reporting or updating requirements.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-22. Deliberate misconduct.

1. This section applies to any:

   a. Licensee;

   b. Certificate holder;

   c. Quality assurance program approval holder;

   d. Applicant for a license, certificate, or quality assurance program approval;

   e. Contractor (including a supplier or consultant) or subcontractor, to any person identified in subdivisions a through d; or

   f. Employee of any person identified in subdivisions a through e.

2. A person identified in subsection 1 who knowingly provides to any entity, listed in subdivisions a through f of subsection 1 any components, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's or applicant's activities subject to article 33-10 may not:

   a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, certificate or approval issued by the department; or

   b. Deliberately submit to the department, a licensee, a certificate holder, quality assurance program approved holder, an applicant

for a license, certificate, or quality assurance program approval, or a licensee's, applicant's, certificate holder's, or quality assurance program approval holder's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the department.

3. A person who violates subsection 2 may be subject to enforcement action.

4. For the purposes of subdivision a of subsection 2, deliberate misconduct by a person means an intentional act or omission that the person knows:

   a. Would cause a licensee, certificate holder, quality assurance program approval holder, or applicant for a license, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order, or any term, condition, or limitation, of any license or certificate issued by the department; or

   b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

APPENDIX A
DETERMINATION OF A_1 and A_2

1. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these rules are given in Table I. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one-tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

2. For individual radionuclides whose identities are known, but which are not listed in Table I, the determination of the values of A_1 and A_2 requires department approval, except that the values of A_1 and A_2 in Table II may be used without obtaining department approval.

3. In the calculations of A_1 and A_2 for a radionuclide not in Table I, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

4. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

   a. For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_I \frac{B(i)}{A_1(i)} \leq 1$$

   Where B(i) is the activity of radionuclude I and A_1(i) is the A_1 value for radionuclide I.

   b. For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_{I} \frac{B(i)}{A_2(i)} \leq 1$$

Where B(i) is the activity of radionuclide I and A_2(i) is the A_2 value for radionuclide I.

c. An A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_{I} \frac{f(i)}{A_1(i)}}$$

Where f(i) is the fraction of activity of nuclide I in the mixture and A_1(i) is the appropriate A_1 value for nuclide I.

d. An A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_{I} \frac{f(i)}{A_2(i)}}$$

Where f(i) is the fraction of activity of nuclide I in the mixture and A_2 (i) is the appropriate A_2 value for nuclide I.

5. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in subsection 4. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

History: Effective June 1, 1992; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

TABLE I

Table I cannot be accurately reproduced for publication.
Users should contact the State Department of Health to obtain a correct copy.

CHAPTER 33-10-14

33-10-14-05. Performance requirements.

1. **Performance criteria for sealed sources.**

   a. Requirements. Sealed sources installed after July 1, 1993:

      (1) Must have a certificate of registration issued under 10 Code of Federal Regulations 32.210.

      (2) Must be doubly encapsulated.

      (3) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator.

      (4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools.

      (5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs b through g.

   b. Temperature. The test source must be held at minus forty degrees Centigrade for twenty minutes, six hundred degrees Centigrade for one hour, and then be subjected to a thermal shock test with a temperature drop from six hundred degrees Centigrade to twenty degrees Centigrade within fifteen seconds.

   c. Pressure. The test source must be twice subjected for at least five minutes to an external pressure (absolute) of two million newtons per square meter.

   d. Impact. A two kilogram steel weight, two and five-tenths centimeters in diameter, must be dropped from a height of one meter onto the test source.

   e. Vibration. The test source must be subjected three times for ten minutes each to vibrations sweeping from twenty-five hertz to five hundred hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for thirty minutes at each resonant frequency found.

f. Puncture. A fifty gram weight and pin, three-tenths centimeter pin diameter, must be dropped from a height of one meter onto the test source.

g. Bend. If the length of the source is more than fifteen times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of two thousand newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

2. **Access control.**

a. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

b. In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

c. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry, while the monitor measures high radiation levels, must activate the alarm described in paragraph b. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

d. Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically

activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

e. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

f. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

g. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator ~~must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material". Panoramic irradiators must also have a sign stating "High radiation area" but the sign~~ must be posted as required by subsection 2 of section 33-10-04.1-13. Radiation postings for panoramic irradiators must comply with the posting requirements of subsection 2 of section 33-10-04.1-13, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

h. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

i. Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

3. **Shielding.**

a. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed two hundredths millisievert [2 millirems] per hour at any location thirty centimeters

or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed one hundred square centimeters having no linear dimension greater than twenty centimeters. Areas where the radiation dose rate exceeds two hundredths millisievert [2 millirems] per hour must be locked, roped off, or posted.

b. The radiation dose at thirty centimeters over the edge of the pool of a pool irradiator may not exceed two hundredths millisievert [2 millirems] per hour when the sources are in the fully shielded position.

c. The radiation dose rate at one meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed two hundredths millisievert [2 millirems] per hour and at five centimeters from the shield may not exceed two-tenths millisievert [20 millirems] per hour.

4. **Fire protection.**

a. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

b. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shutoff valve to control flooding into unrestricted areas.

5. **Radiation monitors.**

a. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

b. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shutoff.

The alarm must be capable of alerting an individual who is prepared to respond promptly.

6. **Control of source movement.**

   a. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

   b. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

   c. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

   d. Each control for a panoramic irradiator must be clearly marked as to its function.

7. **Irradiator pools.**

   a. For licenses initially issued after July 1, 1993, irradiator pools must either:

      (1) Have a watertight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

      (2) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

   b. For licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than five-tenths meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than five-tenths meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

   c. A means must be provided to replenish water losses from the pool.

d. A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

e. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of twenty microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

f. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

g. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed two hundredths millisievert [2 millirems] per hour.

8. **Source rack protection.** If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

9. **Power failures.**

a. If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

b. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

c. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

History: Effective July 1, 1995; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04

33-10-14-06. Design requirements. Irradiators whose construction ~~begins~~ began after July 1, 1993, must meet the design requirements of this section.

1. **Shielding.** For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of

subsection 3 of section 33-10-14-05. If the irradiator will use more than two hundred thousand terabecquerels [5 million curies] of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

2. **Foundations.** For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

3. **Pool integrity.** For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of subdivision b of subsection 7 of section 33-10-14-05, and that metal components are metallurgically compatible with other components in the pool.

4. **Water handling system.** For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of subdivision e of subsection 7 of section 33-10-14-05. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

5. **Radiation monitors.** For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by subdivision a of subsection 5 of section 33-10-14-05. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under subdivision b of subsection 5 of section 33-10-14-08, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

6. **Source rack.** For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and sourceholder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

7. **Access control.** For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of subsection 2 of section 33-10-14-05.

8. **Fire protection.** For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

9. **Source return.** For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than ten seconds.

10. **Seismic.** For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the siesmic requirements of an appropriate source such as American concrete institute standard ACI 318-89, "building code requirements for reinforced concrete", chapter 21, "special provisions for seismic design", or local building codes, if current.

11. **Wiring.** For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

History: Effective July 1, 1995; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04

33-10-14-07. Construction monitoring and acceptance testing. The requirements of this section must be met for irradiators whose construction ~~begins~~ began after July 1, 1993. The requirements must be met prior to loading sources.

1. **Shielding.** For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

2. **Foundations.** For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

3. **Pool integrity.** For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of subdivision b of subsection 7 of section 33-10-14-05.

4. **Water handling system.** For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

5. **Radiation monitors.** For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by subdivision a of subsection 5 of section 33-10-14-05. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet subdivision b of subsection 5 of section 33-10-14-08. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by subdivision b of subsection 5 of section 33-10-14-05.

6. **Source rack.** For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in subsection 8 of section 33-10-14-05 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

7. **Access control.** For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

8. **Fire protection.** For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

9. **Source return.** For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

10. **Computer systems.** For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

11. **Wiring.** For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

History: Effective July 1, 1995; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04

33-10-14-08. Operation of irradiators.

1. **Training.**

   a. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

      (1) The fundamentals of radiation protection applied to irradiators, including the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

      (2) The requirements of chapters 33-10-10 and 33-10-14 that are relevant to the irradiator;

      (3) The operation of the irradiator;

      (4) Those operating and emergency procedures listed in subsection 2 of section 33-10-14-08 that the individual is responsible for performing; and

      (5) Case histories of accidents or problems involving irradiators.

   b. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

   c. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that the individual is to perform.

d. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

(1) Changes in operating and emergency procedures since the last review, if any;

(2) Changes in rules and license conditions since the last review, if any;

(3) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(4) Relevant results of inspections of operator safety performance;

(5) Relevant results of the facility's inspection and maintenance checks; and

(6) A drill to practice an emergency or abnormal event procedure.

e. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that rules, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

f. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in subsection 2 of section 33-10-14-08 that they are expected to perform or comply with, and their proper response to alarms required in this chapter. Tests may be oral.

g. Individuals who must be prepared to respond to alarms required by subdivision b of subsection 2 of section 33-10-14-05, subdivision i of subsection 2 of section 33-10-14-05, subdivision a of subsection 4 of section 33-10-14-05, subdivision a of subsection 5 of section 33-10-14-05, subdivision b of subsection 5 of section 33-10-14-05, and subdivision b of subsection 5 of this section must be trained and tested on how to respond. Each individual must be retested at least ~~once a year~~ annually. Tests may be oral.

2. **Operating and emergency procedures.**

a. The licensee shall have and follow written operating procedures for:

(1) Operation of the irradiator, including entering and leaving the radiation room;

(2) Use of personnel dosimeters;

(3) Surveying the shielding of panoramic irradiators;

(4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(5) Leak testing of sources;

(6) Inspection and maintenance checks required by subsection 6 of section 33-10-14-08;

(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(8) Inspection of movable shielding required by subdivision h of subsection 2 of section 33-10-14-05, if applicable.

b. The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(1) Sources stuck in the unshielded position;

(2) Personnel overexposures;

(3) A radiation alarm from the product exit portal monitor or pool monitor;

(4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

(5) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(6) A prolonged loss of electrical power;

(7) A fire alarm or explosion in the radiation room;

(8) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(10) The jamming of automatic conveyor systems.

c. The licensee may revise operating and emergency procedures without department approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility;

(2) The revisions are consistent with the outline or summary of procedures submitted with the license applications;

(3) The revisions have been reviewed and approved by the radiation safety officer; and

(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

3. **Personnel monitoring.**

a. Irradiator operators shall wear ~~either a film badge or a thermoluminescent dosimeter (TLD)~~ a personnel dosimeter that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The ~~film badge or TLD~~ personnel dosimeter processor must be accredited ~~by the national voluntary laboratory accreditation program~~ for high energy photons in the normal and accident dose ranges (see subdivision c of subsection 1 of section 33-10-04.1-09). Each ~~film badge or TLD~~ personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and ~~TLDs~~ other personnel dosimeters must be processed at least quarterly.

b. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subdivision, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus ~~thirty~~ twenty percent of the true radiation dose.

4. **Radiation surveys.**

a. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

b. If the radiation levels specified in subsection 3 of section 33-10-14-05 are exceeded, the facility must be modified to comply with the requirements in subsection 3 of section 33-10-14-05.

c. Portable radiation survey meters must be calibrated at least annually to an accuracy of plus or minus twenty percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

d. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in chapter 33-10-04.1, table II, column 2 or table III of appendix B, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage".

e. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than five-tenths microsievert [0.05 millirem] per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of five-tenths microsievert [0.05 millirem] per hour.

5. **Detection of leaking sources.**

a. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the department, the United States nuclear regulatory commission, or an agreement state. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested.

The test must be capable of detecting the presence of two hundred becquerels [0.005 microcurie] of radioactive material and must be performed by a person approved by the department, the United States nuclear regulatory commission, or an agreement state to perform the test.

b. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within twenty-four hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

c. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a department, United States nuclear regulatory commission, or agreement state licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a department, United States nuclear regulatory commission, or agreement state licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in table II, column 2, appendix B to chapter 33-10-04.1. (See subsection 5 of section 33-10-04.1-16 for reporting requirements.)

6. **Inspection and maintenance.**

a. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(1) Operability of each aspect of the access control system required by subsection 2 of section 33-10-14-05.

(2) Functioning of the source position indicator required by subdivision b of subsection 6 of section 33-10-14-05.

(3) Operability of the radiation monitor for radioactive contamination in pool water required by subdivision b of subsection 5 of section 33-10-14-08 using a radiation check source, if applicable.

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by subdivision b of subsection 5 of section 33-10-14-05.

(5) Operability of the product exit monitor required by subdivision a of subsection 5 of section 33-10-14-05.

(6) Operability of the emergency source return control required by subdivision c of subsection 6 of section 33-10-14-05.

(7) Leak-tightness of systems through which pool water circulates (visual inspection).

(8) Operability of the heat and smoke detectors and extinguisher system required by subsection 4 of section 33-10-14-05, but without turning extinguishers on.

(9) Operability of the means of pool water replenishment required by subdivision c of subsection 7 of section 33-10-14-05.

(10) Operability of the indicators of high and low pool water levels required by subdivision d of subsection 7 of section 33-10-14-05.

(11) Operability of the intrusion alarm required by subdivision i of subsection 2 of section 33-10-14-05, if applicable.

(12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by subsection 8 of section 33-10-14-05.

(14) Amount of water added to the pool to determine if the pool is leaking.

(15) Electrical wiring on required safety systems for radiation damage.

(16) Pool water conductivity measurements and analysis as required by subdivision b of subsection 7 of section 33-10-14-08.

b. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

7. **Pool water purity.**

a. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below twenty microsiemens per centimeter under normal circumstances. If pool water conductivity rises above twenty microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

b. The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below twenty microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

8. **Attendance during operation.**

a. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

(1) Whenever the irradiator is operated using an automatic product conveyor system; and

(2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

b. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in subdivision g of subsection 1 of section 33-10-14-08 must be onsite.

c. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators;

however, they must have received the training described in subdivisions f and g of subsection 1 of section 33-10-14-08. Static irradiations may be performed without a person present at the facility.

9. **Entering and leaving the radiation room.**

   a. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

   b. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

      (1) Visually inspect the entire radiation room to verify that no one else is in it.

      (2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

   c. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by subdivision b of subsection 5 of section 33-10-14-05 is operating with backup power.

10. **Irradiation of explosive or flammable materials.**

   a. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

   b. Irradiation of more than small quantities of flammable material (flashpoint below 140 degrees Fahrenheit [60 degrees Celsius]) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed

sources or safety systems and without radiation overexposures of personnel.

History: Effective July 1, 1995; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04

33-10-14-09. Records.

1. **Records and retention periods.** The licensee shall maintain the following records at the irradiator for the periods specified.

   a. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the department terminates the license for documents not superseded.

   b. Records of each individual's training, tests, and safety reviews provided to meet the requirements of subdivisions a, b, c, d, f, and g of subsection 1 of section 33-10-14-08 until three years after the individual terminates work.

   c. Records of the annual evaluations of the safety performance of irradiator operators required by subdivision e of subsection 1 of section 33-10-14-08 for three years after the evaluation.

   d. A copy of the current operating and emergency procedures required by subsection 2 of section 33-10-14-08 until superseded or the department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by paragraph 3 of subdivision c of subsection 2 of section 33-10-14-08 retained for three years from the date of the change.

   e. ~~Film badge and TLD results~~ Evaluations of badges required by subsection 3 of section 33-10-14-08 until the department terminates the license.

   f. Records of radiation surveys required by subsection 4 of section 33-10-14-08 for three years from the date of the survey.

   g. Records of radiation survey meter calibrations required by subsection 4 of section 33-10-14-08 and pool water conductivity meter calibrations required by subdivision b of subsection 7 of section 33-10-14-08 until three years from the date of calibration.

   h. Records of the results of leak tests required by subdivision a of subsection 5 of section 33-10-14-08 and the results of contamination checks required by subdivision b of subsection 5 of section 33-10-14-08 for three years from the date of each test.

i. Records of inspection and maintenance checks required by subsection 6 of section 33-10-14-08 for three years.

j. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

k. Records of the receipt, transfer, and disposal of all licensed sealed sources as required by sections 33-10-04.1-15 and 33-10-01-06.

l. Records on the design checks required by section 33-10-14-06 and the construction control checks as required by section 33-10-14-07 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

m. Records related to decommissioning of the irradiator as required by subdivision g of subsection 14 of section 33-10-03-05.

2. **Reports.**

a. In addition to the reporting requirements in chapter 33-10-04.1, the licensee shall report the following events:

(1) Source struck in an unshielded position.

(2) Any fire or explosion in a radiation room.

(3) Damage to the source racks.

(4) Failure of the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation source by the product exit monitor.

(7) Detection of radioactive contamination attributable to licensed radioactive material.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(10) Pool water conductivity exceeding one hundred microsiemens per centimeter.

b. The report must include a telephone report within twenty-four hours as described in paragraph 1 of subdivision c of subsection 5 of section 33-10-04.1-16, and a written report within thirty days as described in paragraph 2 of subdivision c of subsection 5 of section 33-10-04.1-16.

History: Effective July 1, 1995; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-09.1

CHAPTER 33-15-01

33-15-01-04. Definitions. As used in this article, except as otherwise specifically provided or ~~where~~ when the context indicates otherwise, the following words shall have the meanings ascribed to them in this section:

1. "Act" means North Dakota Century Code chapter 23-25.

2. "Air contaminant" means any solid, liquid, gas, or odorous substance or any combination thereof.

3. "Air pollution" means the presence in the outdoor atmosphere of one or more air contaminants in such quantities and duration as is or may be injurious to human health, welfare, or property~~,~~ or animal or plant life, or which unreasonably interferes with the enjoyment of life or property.

4. "Ambient air" means the surrounding outside air.

5. "ASME" means the American society of mechanical engineers.

6. "Coal conversion facility" means any of the following:

   a. An electrical generating plant, and all additions thereto, which processes or converts coal from its natural form into electrical power and which has at least one single electrical energy generation unit with a generator nameplate capacity of twenty-five megawatts or more.

   b. A plant, and all additions thereto, which processes or converts coal from its natural form into a form substantially different in chemical or physical properties, including coal gasification, coal liquefaction, and the manufacture of fertilizer and other products and which uses or is designed to use over five hundred thousand tons of coal per year.

   c. A coal beneficiation plant, and all additions thereto, which improve the physical, environmental, or combustion qualities of coal and are built in conjunction with a facility defined in subdivision a or b.

7. "Control equipment" means any device or contrivance which prevents or reduces emissions.

8. "Department" means the North Dakota state department of health.

9. "Emission" means a release of air contaminants into the ambient air.

10. "Existing" means equipment, machines, devices, articles, contrivances, or installations which are in being on or before July 1, 1970, unless specifically designated within this article; except that any existing

equipment, machine, device, contrivance, or installation which is altered, repaired, or rebuilt after July 1, 1970, must be reclassified as "new" if such alteration, rebuilding, or repair results in the emission of an additional or greater amount of air contaminants.

11. "Federally enforceable" means all limitations and conditions which are enforceable by the administrator of the United States environmental protection agency, including those requirements developed pursuant to title 40, Code of Federal Regulations, parts 60 and 61, requirements within any applicable state implementation plan, any permit requirements established pursuant to title 40, Code of Federal Regulations, 52.21 or under regulations approved pursuant to title 40, Code of Federal Regulations, part 51, subpart I, including operating permits issued under a United States environmental protection agency-approved program that is incorporated into the state implementation plan and expressly requires adherence to any permit issued under such program.

12. "Fuel burning equipment" means any furnace, boiler apparatus, stack, or appurtenances thereto used in the process of burning fuel or other combustible material for the primary purpose of producing heat or power by indirect heat transfer.

13. "Fugitive emissions" means solid airborne particulate matter, fumes, gases, mist, smoke, odorous matter, vapors, or any combination thereof generated incidental to an operation process procedure or emitted from any source other than through a well-defined stack or chimney.

14. "Garbage" means putrescible animal and vegetable wastes resulting from the handling, preparation, cooking, and consumption of food, including wastes from markets, storage facilities, handling, and sale of produce and other food products.

15. "Hazardous waste" has the same meaning as given by chapter 33-24-02.

16. "Heat input" means the aggregate heat content of all fuels whose products of combustion pass through a stack or stacks. The heat input value to be used shall be the equipment manufacturer's or designer's guaranteed maximum input, whichever is greater.

17. "Incinerator" means any article, machine, equipment, device, contrivance, structure, or part of a structure used for the destruction of garbage, rubbish, or other wastes by burning or to process salvageable material by burning.

18. "Industrial waste" means solid waste that is not a hazardous waste regulated under North Dakota Century Code chapter 23-20.3, generated from the combustion or gasification of municipal waste

and from industrial and manufacturing processes. The term does not include municipal waste or special waste.

19. "Inhalable particulate matter" means particulate matter with an aerodynamic diameter less than or equal to a nominal ten micrometers.

20. "Installation" means any property, real or personal, including, but not limited to, processing equipment, manufacturing equipment, fuel burning equipment, incinerators, or any other equipment, or construction, capable of creating or causing emissions.

21. "Multiple chamber incinerator" means any article, machine, equipment, contrivance, structure, or part of a structure used to burn combustible refuse, consisting of two or more refractory lined combustion furnaces in series physically separated by refractory walls, interconnected by gas passage ports or ducts and employing adequate parameters necessary for maximum combustion of the material to be burned.

22. "Municipal waste" means solid waste that includes garbage, refuse, and trash generated by households, motels, hotels, and recreation facilities, by public and private facilities, and by commercial, wholesale, and private and retail businesses. The term does not include special waste or industrial waste.

23. "New" means equipment, machines, devices, articles, contrivances, or installations built or installed on or after July 1, 1970, unless specifically designated within this article, and installations existing at said stated time which are later altered, repaired, or rebuilt and result in the emission of an additional or greater amount of air contaminants.

24. "Opacity" means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

25. "Open burning" means the burning of any matter in such a manner that the products of combustion resulting from the burning are emitted directly into the ambient air without passing through an adequate stack, duct, or chimney.

26. "Particulate matter" means any airborne finely divided solid or liquid material with an aerodynamic diameter smaller than one hundred micrometers.

27. "Particulate matter emissions" means all finely divided solid or liquid material, other than uncombined water, emitted to the ambient air.

28. "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.

29. "Pesticide" includes:

a. Any agent, substance, or mixture of substances intended to prevent, destroy, control, or mitigate any insect, rodent, nematode, predatory animal, snail, slug, bacterium, weed, and any other form of plant or animal life, fungus, or virus, that may infect or be detrimental to persons, vegetation, crops, animals, structures, or households or be present in any environment or which the department may declare to be a pest, except those bacteria, fungi, protozoa, or viruses on or in living man or other animals;

b. Any agent, substance, or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and

c. Any other similar substance so designated by the department, including herbicides, insecticides, fungicides, nematocides, molluscacides, rodenticides, lampreycides, plant regulators, gametocides, post-harvest decay preventatives, and antioxidants.

30. "Petroleum refinery" means an installation that is engaged in producing gasoline, kerosene, distillate fuel oils, residual fuel oils, lubricants, or other products through distillation of petroleum, or through the redistillation, cracking, or reforming of unfinished petroleum derivatives.

31. "PM_{10}" means particulate matter with an aerodynamic diameter less than or equal to a nominal ten micrometers.

32. "PM_{10} emissions" means finely divided solid or liquid material with an aerodynamic diameter less than or equal to a nominal ten micrometers emitted to the ambient air.

33. "Pipeline quality natural gas" means natural gas that contains two grains, or less, of sulfur per one hundred standard cubic feet [2.83 cubic meters].

34. "Premises" means any property, piece of land or real estate, or building.

~~34.~~ 35. "Process weight" means the total weight of all materials introduced into any specific process which may cause emissions. Solid fuels charged will be considered as part of the process weight, but liquid and gaseous fuels and combustion air will not.

~~35.~~ 36. "Process weight rate" means the rate established as follows:

a. For continuous or longrun steady state operations, the total process weight for the entire period of continuous operation or for a typical

portion thereof, divided by the number of hours of such period or portion thereof.

b. For cyclical or batch operations, the total process weight for a period that covers a complete operation or an integral number of cycles, divided by the hours of actual process operation during such a period. ~~Where~~ If the nature of any process or operation or the design of any equipment is such as to permit more than one interpretation of this definition, the interpretation that results in the minimum value for allowable emission shall apply.

~~36.~~ 37. "Radioactive waste" means solid waste containing radioactive material and subject to the requirements of article 33-10.

~~37.~~ 38. "Refuse" means any municipal waste, trade waste, rubbish, or garbage, exclusive of industrial waste, special waste, radioactive waste, hazardous waste, and infectious waste.

~~38.~~ 39. "Rubbish" means nonputrescible solid wastes consisting of both combustible and noncombustible wastes. Combustible rubbish includes paper, rags, cartons, wood, furniture, rubber, plastics, yard trimmings, leaves, and similar materials. Noncombustible rubbish includes glass, crockery, cans, dust, metal furniture, and like materials which will not burn at ordinary incinerator temperatures (one thousand six hundred to one thousand eight hundred degrees Fahrenheit [1144 degrees Kelvin to 1255 degrees Kelvin]).

~~39.~~ 40. "Salvage operation" means any operation conducted in whole or in part for the salvaging or reclaiming of any product or material.

~~40.~~ 41. "Smoke" means small gasborne particles resulting from incomplete combustion, consisting predominantly, but not exclusively, of carbon, ash, and other combustible material, that form a visible plume in the air.

~~41.~~ 42. "Source" means any property, real or personal, or person contributing to air pollution.

~~42.~~ 43. "Source operation" means the last operation preceding emission which operation:

a. Results in the separation of the air contaminant from the process materials or in the conversion of the process materials into air contaminants, as in the case of combustion fuel; and

b. Is not an air pollution abatement operation.

~~43.~~ 44. "Special waste" means solid waste that is not a hazardous waste regulated under North Dakota Century Code chapter 23-20.3 and includes waste generated from energy conversion facilities; waste

from crude oil and natural gas exploration and production; waste from mineral and or mining, beneficiation, and extraction; and waste generated by surface coal mining operations. The term does not include municipal waste or industrial waste.

~~44.~~ 45. "Stack or chimney" means any flue, conduit, or duct arranged to conduct emissions.

~~45.~~ 46. "Standard conditions" means a dry gas temperature of sixty-eight degrees Fahrenheit [293 degrees Kelvin] and a gas pressure of fourteen and seven-tenths pounds per square inch absolute [101.3 kilopascals].

~~46.~~ 47. "Submerged fill pipe" means any fill pipe the discharge opening of which is entirely submerged when the liquid level is six inches [15.24 centimeters] above the bottom of the tank; or when applied to a tank which is loaded from the side, means any fill pipe the discharge opening of which is entirely submerged when the liquid level is one and one-half times the fill pipe diameter in inches [centimeters] above the bottom of the tank.

~~47.~~ 48. "Trade waste" means solid, liquid, or gaseous waste material resulting from construction or the conduct of any business, trade, or industry, or any demolition operation, including wood, wood containing preservatives, plastics, cartons, grease, oil, chemicals, and cinders.

~~48.~~ 49. "Trash" means refuse commonly generated by food warehouses, wholesalers, and retailers which is comprised only of nonrecyclable paper, paper products, cartons, cardboard, wood, wood scraps, and floor sweepings and other similar materials. Trash may not contain more than five percent by volume of each of the following: plastics, animal and vegetable materials, or rubber and rubber scraps. Trash must be free of grease, oil, pesticides, yard waste, scrap tires, infectious waste, and similar substances.

~~49.~~ 50. "Volatile organic compounds" means the definition of volatile organic compounds in 40 Code of Federal Regulations 51.100(s) as it exists on August 1, ~~2000~~ 2001, which is incorporated by reference.

~~50.~~ 51. "Waste classification" means the seven classifications of waste as defined by the incinerator institute of America and American society of mechanical engineers.

History: Amended effective October 1, 1987; January 1, 1989; June 1, 1990; June 1, 1992; March 1, 1994; December 1, 1994; August 1, 1995; January 1, 1996; September 1, 1997; September 1, 1998; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

33-15-01-17. Enforcement.

1. Enforcement action will be consistent with procedures as approved by the United States environmental protection agency.

2. Notwithstanding any other provision in this article, any credible evidence may be used for the purpose of establishing whether a person has violated or is in violation of this article.

   a. Information from the use of the following methods is presumptively credible evidence of whether a violation has occurred at a source:

      (1) ~~An enhanced~~ A compliance assurance monitoring protocol approved for the source pursuant to ~~sections 114(a)(3) and 504(b) of the Federal Clean Air Act [42 U.S.C. 7401, et seq.] or the regulations promulgated thereunder~~ subsection 10 of section 33-15-14-06.

      (2) A monitoring method approved for the source pursuant to paragraph 3 of subdivision a of subsection 5 of section 33-15-14-06 and incorporated in a federally enforceable title V permit to operate.

      (3) Compliance test methods specified in this article.

   b. The following testing, monitoring, and information-gathering methods are presumptively credible testing, monitoring, or information-gathering methods:

      (1) Any federally enforceable monitoring or testing methods, including those under title 40, Code of Federal Regulations, parts 50, 51, 60, 61, 63, and 75.

      (2) Other testing, monitoring, or information-gathering methods that produce information comparable to that produced by any method in paragraph 1 or in subdivision a ~~of subsection 2 of section 33-15-01-17~~.

3. a. No person may knowingly make a false statement, representation, or certification in any application, record, report, plan, or other document filed or required under this article.

b. No person may knowingly falsify, tamper with, or provide inaccurate information regarding a monitoring device or method required under this article.

History: Effective June 1, 1990; amended effective December 1, 1994; September 1, 1997; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

33-15-01-18. Compliance certifications. Notwithstanding any other provision in this article, for the purpose of submission of compliance certifications the owner or operator is not prohibited from using the following in addition to any specified compliance methods:

1. ~~An enhanced~~ A compliance assurance monitoring protocol approved for the source pursuant to ~~sections 114(a)(3) and 504(b) of the Federal Clean Air Act or the regulations promulgated thereunder~~ subsection 10 of section 33-15-14-06.

2. Any other monitoring method approved for the source under paragraph 3 of subdivision a of subsection 5 of section 33-15-14-06 and incorporated into a federally enforceable title V permit to operate.

History: Effective December 1, 1994; amended effective March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

33-15-05-02. Maximum allowable emission of particulate matter from fuel burning equipment used for indirect heating.

1. **General provisions.**

   a. This section applies to installations in which fuel is burned for the primary purpose of producing steam, hot water, hot air, or other indirect heating of liquids, gases, or solids and, in the course of doing so, the products of combustion do not come into direct contact with process materials. Fuels include those such as coal, coke, lignite, coke breeze, fuel oil, and wood but do not include refuse. When any products or byproducts of a manufacturing process are burned for the same purpose or in conjunction with any fuel, the same maximum emission limitations shall apply.

   b. The maximum allowable particulate matter which may be emitted from fuel burning units at a source is determined by the maximum or manufacturer's rated heat input of each unit.

   c. Fuel burning equipment that meets the applicability requirements of subdivision a in which a gaseous fuel is burned alone or in combination with other gaseous fuels is exempt from the emission limitations in subsection 2. Fuel burning equipment that burns a gaseous fuel, or fuels, in combination with other fuels is subject to the emission limitations in subsection 2.

2. **Emission limitations.**

   a. Existing installations. No person shall cause or permit the emission of particulate matter, caused by combustion of fuel in any existing fuel burning equipment, from any stack or chimney in excess of eighty-hundredths pounds of particulates per million British thermal units [344 nanograms per joule] heat input. Provided, however, as technology develops for making new control equipment compatible, both technically and economically, with present plants they shall comply with limitations on emissions of particulate matter from fuel burning installations as outlined in subdivision b when directed by the department.

   b. New installations. No person shall cause or permit the emission of particulate matter, caused by the combustion of fuel in any new fuel burning equipment, from any stack or chimney in excess of the quantity set forth in table 4.

   c. Means shall be provided in all newly constructed units and wherever practicable in existing units to allow the periodic measurement of fly ash and other particulate matter.

d. No person may burn or cause or permit the burning of refuse, including preservative treated wood, in any installation which was designed for the sole purpose of burning fuel unless approved by the department.

e. Existing or new installations, with a heat input of not more than ten million British thermal units per hour and sources with multiple boilers with a total aggregate heat input of not more than ten million British thermal units per hour, shall be exempt from the applicable allowable emission rate set forth in subdivision a or in table 4, respectively. These sources shall be subject to visible emission and ambient air quality standards.

f. Any new or existing source whose heat input is greater than two hundred fifty million British thermal units per hour and is equipped with state-of-the-art control technology capable of complying with the particulate emission limitations of subparagraph 1 of paragraph a of section 60.42 of subpart D of chapter 33-15-12 [40 CFR 60.42(a)(1)] shall comply with such limitations when directed by the department.

g. If any party is aggrieved by the department's decision as referenced in subdivision a or f, that party may request a hearing before the department to review such decision. Such hearing must be conducted according to article 33-22 and North Dakota Century Code chapter 28-32. If a hearing is requested, the emission limitations as referenced in subdivision a or f (whichever is applicable) are not effective until ordered by the department at the conclusion of the hearing process.

Table 4. Maximum Allowable Rates of Emission of Particulate Matter from New Fuel Burning Equipment

Heat Input (H)	Allowable Emission Rate (E)	Heat Input (H)	Allowable Emission Rate (E)
10^6 Btu/hr	lb/10^6 Btu	joules/hr	nanogram/joule
10 or less	0.600	1.05×10^{10}	258
20	0.548	2.11×10^{10}	235
30	0.519	3.16×10^{10}	224
40	0.500	4.22×10^{10}	215
50	0.486	5.27×10^{10}	209
100	0.444	1.05×10^{11}	191

150	0.421	1.58×10^{11}	181
200	0.405	2.11×10^{11}	174
250	0.394	2.64×10^{11}	169

Interpolation and extrapolation of the data in this table shall be accomplished by the use of equations:

$E = 0.811\ H^{-0.131}$ (English units)

$E = 5307\ H^{-0.131}$ (Metric units)

where E = allowable emission rate in lb/million Btu of heat input [nanogram/joule] and H = heat input in millions of Btu/hr [joules/hr].

History: Amended effective October 1, 1987; June 1, 1990; June 1, 1992; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03, 23-25-08

33-15-05-03.3. Other waste incinerators.

1. **Salvage incinerators.** ~~The owner or operator of a new incinerator for salvage of materials of any design capacity shall comply with standards of subsections 2 and 3 of section 33-15-05-03.1.~~ The department may require construction, operational, and recordkeeping standards and procedures for salvage incinerators. No industrial waste, radioactive waste, hazardous waste, or infectious waste may be burned in a salvage incinerator, unless specifically approved by the department. ~~The department may impose one or more of the requirements of subsection 4 of section 33-15-05-03.1 on the owner or operator of a new incinerator for salvage of materials based on factors such as waste charging rate, quantity or type of emissions, material being salvaged, or site circumstances.~~

2. **Air curtain destructors.** The department may require construction, operational, and recordkeeping standards and procedures for air curtain destructors based upon factors such as characteristics and quantities of materials to be destroyed by burning and site location.

3. **Industrial waste and special waste incinerators.** The department may require construction, operational, emission, monitoring, recordkeeping, and reporting standards and procedures for incinerators of industrial waste based upon factors such as characteristics and quantities of the industrial waste and site location.

4. **Crematoriums.**

a. No owner or operator of combustion units operated as a human or animal crematorium or in an animal farm operation for animal disposal may burn any other type or form of materials or solid waste unless specifically approved by the department.

b. No owner or operator of a crematorium may allow to be discharged into the atmosphere any air contaminant, which exhibits an opacity greater than ten percent except that a maximum of twenty percent is permissible for not more than one 6-minute period per hour.

c. A crematorium constructed and operated after August 1, 1995, must be equipped with two or more chambers and with auxiliary fuel burners, designed to assure a temperature in a secondary chamber of at least one thousand six hundred degrees Fahrenheit [871 degrees Celsius] for a minimum of one-second retention time.

d. Monitoring. Each new crematorium must be equipped with a continuous temperature monitor, with readout, to monitor the temperature of the gases exiting the secondary combustion chamber or zone. Each human crematorium installed or reinstalled after September 1, 2002, must be equipped with a temperature recorder.

e. Charging. A crematorium must be charged in accordance with the manufacturer's procedures or recommendations. Deviations from these procedures or recommendations are allowed provided credible evidence has been submitted to the department that indicates the deviations will reduce air contaminant emissions. Such evidence shall be provided prior to implementation of the deviations.

f. Operation. Operators of human crematoriums shall be trained in the proper operation of the unit. A copy of the operation and maintenance manual for the unit shall be available onsite. A trained crematorium operator must be onsite at a human crematorium while the cremation process is taking place.

g. General. The department may establish additional construction, operational, emission, monitoring, recordkeeping, and reporting standards and procedures for crematoriums based upon factors such as quantities of material charged, emissions, and site location.

History: Effective August 1, 1995; amended effective September 1, 1997; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-04, 23-25-04.1

33-15-05-04. Methods of measurement.

1. The reference methods in appendix A to chapter 33-15-12, its replacement or other methods, as approved by the department shall be used to determine compliance with sections 33-15-05-01~~,~~ and 33-15-05-02~~, and 33-15-05-03~~ as follows:

   a. Method 1 for selection of sampling site and sample traverses.

   b. Method 2 for determination of stack gas velocity and volumetric flow rate.

   c. Method 3 for gas analysis.

   d. Method 4 for determination of moisture in the stack gas.

   e. Method 5 for concentration of particulate matter and the associated moisture content. The sampling time for each run shall be at least sixty minutes and the minimum sampling volume shall be thirty dry cubic feet at standard conditions [0.85 dry cubic meter at standard conditions] except that smaller sampling times or volumes when necessitated by process variables or other factors may be approved by the department.

      (1) For each run using method 5 for fuel burning equipment, the emissions expressed in pounds per million British thermal units [nanograms per joule] shall be determined by the following procedures:

$$E = CF_d \frac{(20.9)}{20.9 - \%O_2} \quad \text{or} \quad E = CF_c \frac{(100)}{\%CO_2}$$

      where:

      (a) E = pollutant emission, lb/million Btu [ng/j].

      (b) C = pollutant concentration, lb/dscf [ng/dscm].

      (c) $\%O_2$ = oxygen content by volume, dry basis.

      (d) $\%CO_2$ = carbon dioxide content by volume, dry basis.

      The percent oxygen and percent carbon dioxide shall be determined by using the integrated or grab sampling and analysis procedures of method 3, 3A, 3B, or 3C, as appropriate, by traversing the duct at the same sampling locations used for each run of method 5.

(e) F_d and F_c = factors as listed in method 19 appendix A of ~~40 CFR 60, appendix A~~ chapter 33-15-12.

(2) For each run using method 5 for industrial processes, the emission rate expressed in pounds per hour shall be determined by the equation~~,~~ lb/hr = (Q_s) (c) where:

Q_s = volumetric flow rate of the total effluent in dscf/hr and

c = particulate concentration in lb/dscf.

2. The heat content of fuels shall be determined in accordance with A.S.T.M. methods D2015-66(72) (solid fuels), D240-64(73) (liquid fuels), or D1826-64(70) (gaseous fuels)~~.~~ as applicable.

3. The determination of particulate matter emissions with an aerodynamic diameter less than ten micrometers [PM_{10}] must be made in accordance with the methods established in 40 Code of Federal Regulations, part 51, appendix M~~.~~ as applicable.

History: Amended effective October 1, 1987; June 1, 1992; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

CHAPTER 33-15-06

33-15-06-01. Restriction of emissions of sulfur dioxide from use of fuel.

1. **General provisions.**

   a. Except as provided in subdivision c ~~of this subsection~~, this section applies to any installation in which fuel is burned and in which the sulfur dioxide emissions are substantially due to the content of the fuel burned, and in which the fuel is burned primarily to produce heat.

   b. For purposes of this section, a fuel burning installation is any single fuel burning furnace or boiler or other unit, device, or contrivance in which fuel is burned or any grouping of two or more such furnaces or boilers or other units, devices, or contrivances on the same premises or otherwise located in close proximity to each other and under control of the same person. The capacity of such installations shall be the manufacturer's or designer's guaranteed maximum heat input rate.

   c. This chapter does not apply to installations which are subject to a sulfur dioxide emission limit under chapter 33-15-12.

   d. For purposes of this chapter, equipment at an oil and gas production facility, as defined in chapter 33-15-20, is considered industrial process equipment.

   e. This chapter does not apply to installations that burn pipeline quality natural gas or A.S.T.M. commercial propane alone or in combination with each other. Installations that burn pipeline quality natural gas or A.S.T.M. commercial propane in combination with other fuels are subject to the requirements of this chapter.

2. **Restrictions applicable to fuel burning installations.** No person shall cause or permit the emission of sulfur dioxide to the ambient air from any fuel burning installation in an amount greater than three and zero-tenths pounds of sulfur dioxide per million British thermal units [1290 nanograms/joule] of heat input to the installation on a one-hour-block-average basis. The department may establish alternative averaging periods provided the requirements of chapter 33-15-02 are met. All averaging periods must begin on the hour and averaging periods greater than one hour must be rolling averages.

3. The department shall establish more restrictive emission limits for a source if it is determined that such source is causing the ambient air quality standards of chapter 33-15-02 or the prevention of significant deterioration increments of chapter 33-15-15 for sulfur dioxide to be exceeded. However, the department may consider alternative

measures which will achieve compliance with the ambient air quality standards or prevention of significant deterioration increments.

History: Amended effective June 1, 1992; January 1, 1996; March 1, 2003.
General Authority: NDCC 23-25-03, 28-32-02
Law Implemented: NDCC 23-25-03

33-15-06-03. Methods of measurement. Testing must be done in accordance with the provisions of chapter 33-15-12, as applicable. The reference methods in appendix A to chapter 33-15-12, its replacement or applicable alternative methods as approved by the department, shall be used to determine compliance with this chapter as follows:

1. Method 1 for selection of sampling site and sample traverses.

2. Method 2 for stack gas velocity and volumetric flow rate.

3. Method 3 for gas analysis.

4. Method 4 for moisture content.

5. Method 6, 6A, 6C, and 20, as applicable, for concentration of sulfur dioxide. The minimum sampling time shall be at least sixty minutes per run and a test must consist of three runs.

   ~~a.~~

   For each run using method 6 for fuel burning equipment the emissions expressed in pounds per million British thermal units [nanogram per joule] shall be determined by the following procedures:

$$E = CF_d \frac{20.9}{20.9 - \%O_2} \quad \text{or} \quad E = CF_c \frac{100}{\%CO_2}$$

   where:

   (1) E = pollutant emission, lb/million Btu [ng/j].

   (2) C = pollutant concentrations, lb/dscf [ng/dscm].

   (3) $\%O_2$ = oxygen content by volume, dry basis.

   (4) $\%CO_2$ = carbon dioxide content by volume, dry basis.

   The percent oxygen and percent carbon dioxide shall be determined by using the integrated sampling and analysis procedures of method 3.

(5) F_d and F_c = factors listed in ~~the following table:~~ method 19 of appendix A of chapter 33-15-12.

~~F FACTORS FOR VARIOUS FUELS~~

FUEL TYPE	F_d dscf/10^6 Btu	F_c scf/10^6 Btu
Coal		
Anthracite	10140	1980
Bituminous	9820	1810
Lignite	9900	1920
Oil	9220	1430
Gas		
Natural	8740	1040
Propane	8740	1200
Butane	8740	1260
Wood	9280	1860
Wood bark	9640	1840

For facilities firing combinations of fuels the F_d or F_c factors designated in this section shall be prorated in accordance with the applicable formula as follows:

$$F_d = \sum_{i=1}^{n} x_i \, F_i \, (F_d)_i \text{ or } F_c = \sum_{i=1}^{n} x_i \, (F_c)_i$$

where:

x_i = the fraction of total heat input derived from each type of fuel.

F_i $(F_d)_i$ or $(F_c)_i$ = the applicable F_d or F_c factor for each fuel type.

n = the number of fuels being burned in combination.

History: Amended effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

CHAPTER 33-15-12

33-15-12-01.1. Scope. Except as noted below the title of the subpart, the subparts and appendices of title 40, Code of Federal Regulations, part 60, as they exist on ~~August 1, 2000~~ January 31, 2002, which are listed under section 33-15-12-02 are incorporated into this chapter by reference. Any changes to the standards of performance are listed below the title of the standard.

History: Effective June 1, 1992; amended effective December 1, 1994; January 1, 1996; September 1, 1997; September 1, 1998; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

33-15-12-02. Standards of performance.

Subpart A - General provisions.

*60.2. The definition of administrator is deleted and replaced with the following:

Administrator means the department except for those duties that cannot be delegated by the United States environmental protection agency. For those duties that cannot be delegated, administrator means the department and the administrator of the United States environmental protection agency.

Subpart C - Emission guidelines and compliance times.

Subpart Cc - Emissions guidelines and compliance times for municipal solid waste landfills.

Designated facilities to which this subpart applies shall comply with the requirements for state plan approval in 40 CFR parts 60.33c, 60.34c, and 60.35c, except that quarterly surface monitoring for methane under part 60.34c shall only be required during the second, third, and fourth quarters of the calendar year.

Designated facilities under this subpart shall:

1. Submit a final control plan for department review and approval within twelve months of the date of the United States environmental protection agency's approval of this rule, or within twelve months of becoming subject to this rule, whichever occurs later.

2. Award contracts for control systems/process modification within twenty-four months of the date of the United States environmental protection agency's approval of this rule, or within twenty-four months of becoming subject to the rule, whichever occurs later.

3. Initiate onsite construction or installation of the air pollution control device or process changes within twenty-seven months of the date of the United States environmental protection agency's approval of this rule, or within twenty-seven months of becoming subject to the rule, whichever occurs later.

4. Complete onsite construction or installation of the air pollution control device or devices or process changes within twenty-nine months of the United States environmental protection agency's approval of this rule, or within twenty-nine months of becoming subject to the rule, whichever is later.

5. Conduct the initial performance test within one hundred eighty days of the installation of the collection and control equipment. A notice of intent to conduct the performance test must be submitted to the department at least thirty days prior to the test.

6. Be in final compliance within thirty months of the United States environmental protection agency's approval of this rule, or within thirty months of becoming subject to the rule, whichever is later.

Subpart Ce - Emission guidelines and compliance times for hospital/medical/infectious waste incinerators.

Except as noted below, designated facilities to which this rule applies shall comply with the minimum requirements for state plan approval listed in subpart Ce.

*60.32e(i) The following is added:

Title V permit to operate applications shall be submitted by September 15, 1999.

*60.39e(a) is deleted in its entirety.

*60.39e(b) is deleted in its entirety and replaced with the following:

(b) Except as provided in paragraphs c and d of this section, designated facilities shall comply with all requirements of this subpart within one year of the United States environmental protection agency's approval of the state plan for hospital/medical/infectious waste incinerators regardless of whether a designated facility is identified in the state plan. Owners or operators of designated facilities who will cease operation of their incinerator to comply with this rule shall notify the department of their intention within six months of state plan approval.

*60.39e(c) is deleted in its entirety and replaced with the following:

(c) Owners or operators of designated facilities planning to install the necessary air pollution control equipment to comply with the applicable requirements may petition the department for an extension of the compliance time of up to three years after the United States environmental protection agency's approval of the state plan, but not later than September 16, 2002, provided the facility owner or operator complies with the following:

1. Submits a petition to the department for site specific operating parameters under 40 CFR 60.56c(i) of subpart Ec within thirty months of approval of the state plan and sixty days prior to the performance test.

2. Provides proof to the department of a contract for obtaining services of an architectural or engineering firm or architectural and engineering firm regarding the air pollution control device within nine months of state plan approval.

3. Submits design drawings to the department of the air pollution control device within twelve months of state plan approval.

4. Submits to the department a copy of the purchase order or other documentation indicating an order has been placed for the major components of the air pollution control device within sixteen months after state plan approval.

5. Submits to the department the schedule for delivery of the major components of the air pollution control device within twenty months after state plan approval.

6. Begins initiation of site preparation for installation of the air pollution control device within twenty-two months after state plan approval.

7. Begins initiation of installation of the air pollution control device within twenty-five months after state plan approval.

8. Starts up the air pollution control device within twenty-eight months after state plan approval.

9. Notifies the department of the performance test thirty days prior to the test.

10. Conducts the performance test within one hundred eighty days of the installation of the air pollution control device.

11. Submits a performance test report which demonstrates compliance within thirty-six months of state plan approval.

*60.39e(d) is deleted in its entirety and replaced with the following:

1. Designated facilities petitioning for an extension of the compliance time in paragraph b of this section shall:

    i. Within six months after the United States environmental protection agency's approval of the state plan, submit documentation of the analyses undertaken to support the need for more than one year to comply, including an explanation of why up to three years after United States environmental protection agency approval of the state plan is sufficient to comply with this subpart while one year is not. The documentation shall also include an evaluation of the option to transport the waste offsite to a commercial medical waste treatment and disposal facility on a temporary or permanent basis; and

    ii. Documentation of measurable and enforceable incremental steps of progress to be taken toward compliance with this subpart.

2. The department shall review any petitions for the extension of compliance times within thirty days of receipt of a complete petition and make a decision regarding approval or denial. The department shall notify the petitioner in writing of its decision within forty-five days of the receipt of the petition. All extension approvals must include incremental steps of progress. For those sources planning on installing air pollution control equipment to comply with this subpart, the incremental steps of progress included in 40 CFR 60.39e(c) shall be included as conditions of approval of the extension.

3. Owners or operators of facilities which received an extension to the compliance time in this subpart shall be in compliance with the applicable requirements on or before the date three years after United States environmental protection agency approval of the state plan but not later than September 16, 2002.

*60.39e(f) is deleted in its entirety.

After the compliance dates specified in this subpart, an owner or operator of a facility to which this subpart applies shall not operate any such unit in violation of this subpart.

Subpart D - Standards of performance for fossil-fuel fired steam generators for which construction is commenced after August 17, 1971.

Subpart Da - Standards of performance for electric utility steam generating units for which construction is commenced after September 18, 1978.

Subpart Db - Standards of performance for industrial-commercial-institutional steam generating units.

Subpart Dc - Standards of performance for small industrial-commercial-institutional steam generating units.

Subpart E - Standards of performance for incinerators.

Subpart Ea - Standards of performance for municipal waste combustors for which construction is commenced after December 20, 1989, and on or before September 20, 1994.

Subpart Ec - Standards of performance for hospital/medical/infectious waste incinerators for which construction is commenced after June 20, 1996.

Subpart F - Standards of performance for portland cement plants.

Subpart G - Standards of performance for nitric acid plants.

Subpart H - Standards of performance for sulfuric acid plants.

Subpart I - Standards of performance for hot mix asphalt ~~concrete plants~~ facilities.

Subpart J - Standards of performance for petroleum refineries.

Subpart K - Standards of performance for storage vessels for petroleum liquids for which construction, reconstruction, or modification commenced after June 11, 1973, and prior to May 19, 1978.

*60.110(c) is deleted in its entirety and replaced with the following:

(c) Any facility under part 60.110(a) that commenced construction, reconstruction, or modification after July 1, 1970, and prior to May 19, 1978, is subject to the requirements of this subpart.

Subpart Ka - Standards of performance for storage vessels for petroleum liquids for which construction, reconstruction, or modification commenced after May 18, 1978, and prior to July 23, 1984.

Subpart Kb - Standards of performance for volatile organic liquid storage vessels (including petroleum liquid storage vessels) for which construction, reconstruction, or modification commenced after July 23, 1984.

Subpart L - Standards of performance for secondary lead smelters.

Subpart M - Standards of performance for secondary brass and bronze production plants.

Subpart N - Standards of performance for primary emissions from basic oxygen process furnaces for which construction is commenced after June 11, 1973.

Subpart Na - Standards of performance for secondary emissions from basic oxygen process steelmaking facilities for which construction is commenced after January 20, 1983.

Subpart O - Standards of performance for sewage treatment plants.

Subpart P - Standards of performance for primary copper smelters.

Subpart Q - Standards of performance for primary zinc smelters.

Subpart R - Standards of performance for primary lead smelters.

Subpart S - Standards of performance for primary aluminum reduction plants.

Subpart T - Standards of performance for the phosphate fertilizer industry: wet-process phosphoric acid plants.

Subpart U - Standards of performance for the phosphate fertilizer industry: superphosphoric acid plants.

Subpart V - Standards of performance for the phosphate fertilizer industry: diammonium phosphate plants.

Subpart W - Standards of performance for the phosphate fertilizer industry: triple superphosphate plants.

Subpart X - Standards of performance for the phosphate fertilizer industry: granular triple superphosphate storage facilities.

Subpart Y - Standards of performance for coal preparation plants.

Subpart Z - Standards of performance for ferroalloy production facilities.

Subpart AA - Standards of performance for steel plants: electric arc furnaces: constructed after October 21, 1974, and before August 17, 1983.

Subpart AAa - Standards of performance for steel plants: electric arc furnaces and argon-oxygen decarburization vessels constructed after August 17, 1983.

Subpart BB - Standards of performance for kraft pulp mills.

Subpart CC - Standards of performance for glass manufacturing plants.

Subpart DD - Standards of performance for grain elevators.

Subpart EE - Standards of performance for surface coatings of metal furniture.

Subpart FF - [Reserved]

Subpart GG - Standards of performance for stationary gas turbines.

Subpart HH - Standards of performance for lime manufacturing plants.

Subpart KK - Standards of performance for lead-acid battery manufacturing plants.

Subpart LL - Standards of performance for metallic mineral processing plants.

Subpart MM - Standards of performance for automobile and light-duty truck surface coating operations.

Subpart NN - Standards of performance for phosphate rock plants.

Subpart PP - Standards of performance for ammonium sulfate manufacture.

Subpart QQ - Standards of performance for the graphic arts industry: publication rotogravure printing.

Subpart RR - Standards of performance for pressure-sensitive tape and label surface coating operations.

Subpart SS - Standards of performance for industrial surface coating: large appliances.

Subpart TT - Standards of performance for metal coil surface coating.

Subpart UU - Standards of performance for asphalt processing and asphalt roofing manufacture.

Subpart VV - Standards of performance for equipment leaks of volatile organic compound (VOC) emissions in the synthetic organic chemicals manufacturing industry.

Subpart WW - Standards of performance for the beverage can surface coating industry.

Subpart XX - Standards of performance for bulk gasoline terminals.

Subpart AAA - Standards of performance for new residential wood heaters.

Subpart BBB - Standards of performance for the rubber tire manufacturing industry.

Subpart CCC - [Reserved]

Subpart DDD - Standards of performance for volatile organic compound (VOC) emissions for the polymer manufacturing industry.

Subpart EEE - [Reserved]

Subpart FFF - Standards of performance for flexible vinyl and urethane coating and printing.

Subpart GGG - Standards of performance for equipment leaks of volatile organic compound (VOC) emissions in petroleum refineries.

Subpart HHH - Standards of performance for synthetic fiber production facilities.

Subpart III - Standards of performance for volatile organic compound (VOC) emissions from the synthetic organic chemical manufacturing industry (SOCMI) air oxidation unit processes.

Subpart JJJ - Standards of performance for petroleum drycleaners.

Subpart KKK - Standards of performance for equipment leaks of volatile organic compound (VOC) emissions from onshore natural gas processing plants.

Subpart LLL - Standards of performance for onshore natural gas processing; SO_2 emissions.

Subpart NNN - Standards of performance for volatile organic compound (VOC) emissions from synthetic organic chemical manufacturing industry (SOCMI) distillation operations.

Subpart OOO - Standards of performance for nonmetallic mineral processing plants.

Subpart PPP - Standards of performance for wool fiberglass insulation manufacturing plants.

Subpart QQQ - Standards of performance for volatile organic compound (VOC) emissions from petroleum refinery wastewater systems.

Subpart RRR - Standards of performance for volatile organic compound (VOC) emissions from synthetic organic chemical manufacturing industry (SOCMI) reactor processes.

Subpart SSS - Standards of performance for magnetic tape coating facilities.

Subpart TTT - Standards of performance for industrial surface coating: surface coating of plastic parts for business machines.

Subpart UUU - Standards of performance for calciners and dryers in mineral industries.

Subpart VVV - Standards of performance for polymetric coating of supporting substrates facilities.

Subpart WWW - Standards of performance for municipal solid waste landfills.

Subpart AAAA - Standards of performance for small municipal waste combustion units for which construction is commenced after August 30, 1999, or for which modification or reconstruction is commenced after June 6, 2001.

Subpart CCCC - Standards of performance for commercial and industrial solid waste incineration units for which construction is commenced after November 30, 1999, or for which modification or reconstruction is commenced on or after June 1, 2001.

Subpart DDDD - Emission guidelines and compliance times for commercial and industrial solid waste incinerator units that commenced construction on or before November 30, 1999.

Except as provided below, designated facilities to which this rule applies shall comply with 40 CFR 60.2575 through 60.2875, including tables 1 through 5.

In the rule, you means the owner or operator of a commercial or industrial solid waste incineration unit.

Table 1 of the rule is deleted and replaced with the following:

Table 1 to Subpart DDDD - Model Rule Increments of Progress and Compliance Schedules	
Comply with these increments of progress	By these dates
Increment 1 - Submit final control plan	One year after EPA approval of the state plan or December 1, 2004, whichever comes first.
Increment 2 - Final compliance	Three years after EPA approval of the state plan or December 1, 2005, whichever comes first.

Appendix A - Test methods.

Appendix B - Performance specifications.

Appendix C - Determination of emission rate changes.

Appendix D - Required emission inventory information.

Appendix E - [Reserved]

Appendix F - Quality assurance procedures.

Appendix I - Removable label and owner's manual.

History: Effective June 1, 1992; amended effective March 1, 1994; December 1, 1994; January 1, 1996; September 1, 1997; September 1, 1998; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

33-15-14-02. Permit to construct.

1. **Permit to construct required.** No construction, installation, or establishment of a new stationary source within a source category designated in section 33-15-14-01 may be commenced unless the owner or operator thereof shall file an application for, and receive, a permit to construct in accordance with this chapter. This requirement shall also apply to any source for which a federal standard of performance has been promulgated prior to such filing of an application for a permit to construct. A list of sources for which a federal standard has been promulgated, and the standards which apply to such sources, must be available at the department's offices.

   The initiation of activities that are exempt from the definition of construction, installation, or establishment in section 33-15-14-01.1, prior to obtaining a permit to construct, are at the owner's or operator's own risk. These activities have no impact on the department's decision to issue a permit to construct. The initiation or completion of such activities conveys no rights to a permit to construct under this section.

2. **Application for permit to construct.**

   a. Application for a permit to construct a new installation or source must be made by the owner or operator thereof on forms furnished by the department.

   b. A separate application is required for each new installation or source subject to this chapter.

   c. Each application must be signed by the applicant, which signature shall constitute an agreement that the applicant will assume responsibility for the construction or operation of the new installation or source in accordance with this article and will notify the department, in writing, of the startup of operation of such source.

3. **Alterations to source.**

   a. The addition to or enlargement of or replacement of or alteration in any stationary source, already existing, which is undertaken pursuant to an approved compliance schedule for the reduction of emissions therefrom, shall be exempt from the requirements of this section.

   b. Any physical change in, or change in the method of operation of, a stationary source already existing which increases or may increase the emission rate or increase the ambient concentration by an

amount greater than that specified in subdivision a of subsection 5 of any pollutant for which an ambient air quality standard has been promulgated under this article or which results in the emission of any such pollutant not previously emitted must be considered to be construction, installation, or establishment of a new source, except that:

(1) Routine maintenance, repair, and replacement may not be considered a physical change.

(2) The following may not be considered a change in the method of operation:

(a) An increase in the production rate, if such increase does not exceed the operating design capacity of the source and it is not limited by a permit condition.

(b) An increase in the hours of operation if it is not limited by a permit condition.

(c) Changes from one operating scenario to another provided the alternative operating scenarios are identified and approved in a permit to operate.

(d) Trading of emissions within a facility provided:

[1] These trades have been identified and approved in a permit to operate; and

[2] The total facility emissions do not exceed the facility emissions cap established in the permit to operate.

(e) Trading and utilizing acid rain allowances provided compliance is maintained with all other applicable requirements.

c. Any owner or operator of a source who requests an increase in the allowable sulfur dioxide emission rate for the source pursuant to section 33-15-02-07 shall demonstrate through a dispersion modeling analysis that the revised allowable emissions will not cause or contribute to a violation of the national ambient air quality standards for sulfur oxides (sulfur dioxide) or the prevention of significant deterioration increments for sulfur dioxide. The owner or operator shall also demonstrate that the revised allowable emission rate will not violate any other requirement of this article or the Federal Clean Air Act. Requests for emission limit changes shall be subject to review by the public and the environmental protection agency in accordance with subsection 6.

4. **Submission of plans - Deficiencies in application.** As part of an application for a permit to construct, the department may require the submission of plans, specifications, siting information, emission information, descriptions and drawings showing the design of the installation or source, the manner in which it will be operated and controlled, the emissions expected from it, and the effects on ambient air quality. Any additional information, plans, specifications, evidence, or documentation that the department may require must be furnished upon request. Within twenty days of the receipt of the application, the department shall advise the owner or operator of the proposed source of any deficiencies in the application. In the event of a deficiency, the date of receipt of the application is the date upon which all requested information is received.

   a. Determination of the effects on ambient air quality as may be required under this section must be based on the applicable requirements specified in the "Guideline on Air Quality Models (Revised)" (United States environmental protection agency, office of air quality planning and standards, Research Triangle Park, North Carolina 27711) as supplemented by the "North Dakota Guideline for Air Quality Modeling Analyses" (North Dakota state department of health, division of environmental engineering). These documents are incorporated by reference.

   b. When an air quality impact model specified in the documents incorporated by reference in subdivision a is inappropriate, the model may be modified or another model substituted provided:

      (1) Any modified or nonguideline model must be subject to notice and opportunity for public comment under subsection 6.

      (2) The applicant must provide to the department adequate information to evaluate the applicability of the modified or nonguideline model. Such information must include, but is not limited to, methods like those outlined in the "Interim Procedures for Evaluating Air Quality Models (Revised)" (United States environmental protection agency, office of air quality planning and standards, Research Triangle Park, North Carolina 27711).

      (3) Written approval from the department must be obtained for any modification or substitution.

      (4) Written approval from the United States environmental protection agency must be obtained for any modification or substitution prior to the granting of a permit under this chapter.

5. **Review of application - Standard for granting permits to construct.** The department shall review any plans, specifications, and other information submitted in application for a permit to construct and from such review shall, within ~~thirty~~ ninety days of the receipt of the completed application, make the following preliminary determinations:

   a. Whether the proposed project will be in accord with this article, including whether the operation of any new stationary source at the proposed location will cause or contribute to a violation of any applicable ambient air quality standard. A new stationary source will be considered to cause or contribute to a violation of an ambient air quality standard when such source would, at a minimum, exceed the following significance levels at any locality that does not or would not meet the applicable ambient standard:

Contaminant	Averaging Time (hours)				
	Annual ($\mu g/m^3$)	24 ($\mu g/m^3$)	8 ($\mu g/m^3$)	3 ($\mu g/m^3$)	1 ($\mu g/m^3$)
SO_2	1.0	5		25	25
PM_{10}	1.0	5			
NO_2	1.0				25
CO			500		2000

   b. Whether the proposed project will provide all ~~known available~~ necessary and reasonable methods of emission control. Whenever a standard of performance is applicable to the source, compliance with this criterion will require provision for emission control which will, at least, satisfy such standards.

6. **Public participation - Final action on application.**

   a. The following source categories are subject to the public participation procedures under this subsection:

      (1) Those affected facilities designated under chapter 33-15-13.

      (2) New sources that will be required to obtain a permit to operate under section 33-15-14-06.

      (3) Modifications to an existing facility which will increase the potential to emit from the facility by the following amounts:

         (a) One hundred tons [90.72 metric tons] per year or more of particulate matter, sulfur dioxide, nitrogen oxides, hydrogen sulfide, carbon monoxide, or volatile organic compounds;

(b) Ten tons [9.07 metric tons] per year or more of any contaminant listed under section 112(b) of the Federal Clean Air Act; or

(c) Twenty-five tons [22.68 metric tons] per year or more of any combination of contaminants listed under section 112(b) of the Federal Clean Air Act.

(4) Sources which the department has determined to have a major impact on air quality.

(5) Those for which a request for a public comment period has been received from the public.

(6) Sources for which a significant degree of public interest exists regarding air quality issues.

(7) Those sources which request a federally enforceable permit which limits their potential to emit.

b. With respect to the permit to construct application, the department shall:

(1) Within ninety days of receipt of a complete application, make a preliminary determination concerning issuance of a permit to construct.

(2) Within ninety days of the receipt of the complete application, make available in at least one location in the county or counties in which the proposed project is to be located, a copy of its preliminary determinations and copies of or a summary of the information considered in making such preliminary determinations.

(3) Publish notice to the public by prominent advertisement, within ninety days of the receipt of the complete application, in the region affected, of the opportunity for written comment on the preliminary determinations. The public notice must include the proposed location of the source.

(4) Within ninety days of the receipt of the complete application, deliver a copy of the notice to the applicant and to officials and agencies having cognizance over the locations where the source will be situated as follows: the chief executive of the city and county; any comprehensive regional land use planning agency; and any state, federal land manager, or Indian governing body whose lands will be significantly affected by the source's emissions.

(5) Within ninety days of receipt of a complete application, provide a copy of the proposed permit and all information considered in the development of the permit and the public notice to the regional administrator of the United States environmental protection agency.

(6) Allow thirty days for public comment.

(7) Consider all public comments properly received, in making the final decision on the application.

(8) Allow the applicant to submit written responses to public comments received by the department. The applicant's responses must be submitted to the department within twenty days of the close of the public comment period.

(9) Take final action on the application within thirty days of the applicant's response to the public comments.

(10) Provide a copy of the final permit, if issued, to the applicant, the regional administrator of the United States environmental protection agency, and anyone who requests a copy.

c. For those sources subject to the requirements of chapter 33-15-15, the public participation procedures under subsection 5 of section 33-15-15-01 shall be followed.

7. **Denial of permit to construct.** If, after review of all information received, including public comment with respect to any proposed project, the department makes the determination of any one of subdivision a or b of subsection 5 in the negative, it shall deny the permit and notify the applicant, in writing, of the denial to issue a permit to construct.

   If a permit to construct is denied, the construction, installation, or establishment of the new stationary source shall be unlawful. No permit to construct or modify may be granted if such construction, or modification, or installation, will result in a violation of this article.

8. **Issuance of permit to construct.** If, after review of all information received, including public comment with respect to any proposed project, the department makes the determination of subdivision a or b of subsection 5 in the affirmative, the department shall issue a permit to construct. The permit may provide for conditions of operation as provided in subsection 9.

9. **Permit to construct - Conditions.** The department may impose any reasonable conditions upon a permit to construct, including conditions concerning:

a. Sampling, testing, and monitoring of the facilities or the ambient air or both.

b. Trial operation and performance testing.

c. Prevention and abatement of nuisance conditions caused by operation of the facility.

d. Recordkeeping and reporting.

e. Compliance with applicable rules and regulations in accordance with a compliance schedule.

f. Limitation on hours of operation, production rate, processing rate, or fuel usage when necessary to assure compliance with this article.

The violation of any conditions so imposed may result in revocation or suspension of the permit or other appropriate enforcement action.

10. **Scope.**

a. The issuance of a permit to construct for any source does not affect the responsibility of an owner or operator to comply with applicable portions of a control strategy affecting the source.

b. A permit to construct shall become invalid if construction is not commenced within eighteen months after receipt of such permit, if construction is discontinued for a period of eighteen months or more; or if construction is not completed within a reasonable time. The department may extend the eighteen-month period upon a satisfactory showing that an extension is justified. This provision does not apply to the time period between construction of the approved phases of a phased construction project; each phase must commence construction within eighteen months of the projected and approved commencement date. In cases of major construction projects involving long lead times and substantial financial commitments, the department may provide by a condition to the permit a time period greater than eighteen months when such time extension is supported by sufficient documentation by the applicant.

11. **Transfer of permit to construct.** To ensure the responsible owners or operators, or both, are identified, the holder of a permit to construct may not transfer such permit without prior approval of the department.

12. **[Reserved]**

13. **Exemptions.** A permit to construct is not required for the following stationary sources provided there is no federal requirement for a permit or approval for construction or operation and there is no applicable new source performance standard, or national emission standard for hazardous air pollutants.

a. Maintenance, structural changes, or minor repair of process equipment, fuel burning equipment, control equipment, or incinerators which do not change capacity of such process equipment, fuel burning equipment, control equipment, or incinerators and which do not involve any change in the quality, nature, or quantity of emissions therefrom.

b. Fossil fuel burning equipment, other than smokehouse generators, which meet all of the following criteria:

(1) The heat input per unit does not exceed ten million British thermal units per hour.

(2) The total aggregate heat input from all equipment does not exceed ten million British thermal units per hour.

(3) The actual emissions, as defined in chapter 33-15-15, from all equipment do not exceed twenty-five tons [22.67 metric tons] per year of any air contaminant and the potential to emit any air contaminant for which an ambient air quality standard has been promulgated in chapter 33-15-02 is less than one hundred tons [90.68 metric tons] per year.

c. (1) Any single internal combustion engine with less than five hundred brake horsepower, or multiple engines with a combined brake horsepower rating less than five hundred brake horsepower.

(2) Any single internal combustion engine with a maximum rating of less than one thousand brake horsepower, or multiple engines with a combined brake horsepower rating of less than one thousand brake horsepower, and which operates a total of five hundred hours or less in a rolling twelve-month period.

(3) The exemptions listed in paragraphs 1 and 2 do not apply to engines that are a utility unit as defined in section 33-15-21-08.1.

d. Bench scale laboratory equipment used exclusively for chemical or physical analysis or experimentation.

e. Portable brazing, soldering, or welding equipment.

f. The following equipment:

(1) Comfort air-conditioners or comfort ventilating systems which are not designed and not intended to be used to remove emissions generated by or released from specific units or equipment.

(2) Water cooling towers and water cooling ponds unless used for evaporative cooling of process water, or for evaporative cooling of water from barometric jets or barometric condensers or used in conjunction with an installation requiring a permit.

(3) Equipment used exclusively for steam cleaning.

(4) Porcelain enameling furnaces or porcelain enameling drying ovens.

(5) Unheated solvent dispensing containers or unheated solvent rinsing containers of sixty gallons [227.12 liters] capacity or less.

(6) Equipment used for hydraulic or hydrostatic testing.

g. The following equipment or any exhaust system or collector serving exclusively such equipment:

(1) Blast cleaning equipment using a suspension of abrasive in water.

(2) Bakery ovens ~~where~~ if the products are edible and intended for human consumption.

(3) Kilns for firing ceramic ware, heated exclusively by gaseous fuels, singly or in combinations, and electricity.

(4) Confection cookers ~~where~~ if the products are edible and intended for human consumption.

(5) Drop hammers or hydraulic presses for forging or metalworking.

(6) Diecasting machines.

(7) Photographic process equipment through which an image is reproduced upon material through the use of sensitized radiant energy.

(8) Equipment for drilling, carving, cutting, routing, turning, sawing, planing, spindle sanding, or disc sanding of wood or wood products, which is located within a facility that does not vent to the outside air.

(9) Equipment for surface preparation of metals by use of aqueous solutions, except for acid solutions.

(10) Equipment for washing or drying products fabricated from metal or glass; provided, that no volatile organic materials are used in the process and that no oil or solid fuel is burned.

(11) Laundry dryers, extractors, or tumblers for fabrics cleaned with only water solutions of bleach or detergents.

h. Natural draft hoods or natural draft ventilators.

i. Containers, reservoirs, or tanks used exclusively for:

(1) Dipping operations for coating objects with oils, waxes, or greases, ~~where~~ if no organic solvents are used.

(2) Dipping operations for applying coatings of natural or synthetic resins which contain no organic solvents.

(3) Storage of butane, propane, or liquefied petroleum or natural gas.

(4) Storage of lubricating oils.

(5) Storage of petroleum liquids except those containers, reservoirs, or tanks subject to the air pollution control requirements of chapter 33-15-12. The owner or operator must still provide notification as required in section 33-15-12-02, subpart A.

j. Gaseous fuel-fired or electrically heated furnaces for heat treating glass or metals, the use of which does not involve molten materials.

k. Crucible furnaces, pot furnaces, or induction furnaces, with a capacity of one thousand pounds [453.59 kilograms] or less each, unless otherwise noted, in which no sweating or distilling is conducted, nor any fluxing conducted utilizing chloride, fluoride, or ammonium compounds, and from which only the following metals are poured or in which only the following metals are held in a molten state:

(1) Aluminum or any alloy containing over fifty percent aluminum; provided, that no gaseous chlorine compounds, chlorine, aluminum chloride, or aluminum fluoride are used.

(2) Magnesium or any alloy containing over fifty percent magnesium.

(3) Lead or any alloy containing over fifty percent lead, in a furnace with a capacity of five hundred fifty pounds [249.48 kilograms] or less.

(4) Tin or any alloy containing over fifty percent tin.

(5) Zinc or any alloy containing over fifty percent zinc.

(6) Copper.

(7) Precious metals.

l. Open burning activities within the scope of section 33-15-04-02.

m. Flares used to indicate some danger to the public.

n. Sources or alterations to a source which are of minor significance as determined by the department.

o. Oil and gas production facilities as defined in chapter 33-15-20 which are not a major source as defined in subdivision n of subsection 1 of section 33-15-14-06.

14. **Performance and emission testing.**

a. Emission tests or performance tests or both shall be conducted by the owner or operator of a facility and data reduced in accordance with the applicable procedure, limitations, standards, and test methods established by this article. Such tests must be conducted under the owner's or operator's permit to construct, and such permit is subject to the faithful completion of the test in accordance with this article.

b. All dates and periods of trial operation for the purpose of performance or emission testing pursuant to a permit to construct must be approved in advance by the department. Trial operation shall cease if the department determines, on the basis of the test results, that continued operation will result in the violation of this article. Upon completion of any test conducted under a permit to construct, the department may order the cessation of the operation of the tested equipment or facility until such time as a permit to operate has been issued by the department.

c. Upon review of the performance data resulting from any test, the department may require the installation of such additional control equipment as will bring the facility into compliance with this article.

d. Nothing in this article may be construed to prevent the department from conducting any test upon its own initiative, or from requiring the owner or operator to conduct any test at such time as the department may determine.

15. **Responsibility to comply.**

a. Possession of a permit to construct does not relieve any person of the responsibility to comply with this article.

b. The exemption of any stationary source from the requirements of a permit to construct by reason of inclusion in subsection 13 does not relieve the owner or operator of such source of the responsibility to comply with any other applicable portions of this article.

16. **Portable sources.** Sources which are designated to be portable and which are not subject to the requirements of chapter 33-15-15 are exempt from requirements to obtain a permit to construct. The owner or operator shall submit an application for a permit to operate prior to initiating operations.

17. **Registration of exempted stationary sources.** The department may require that the owner or operator of any stationary source exempted under subsection 13 shall register the source with the department within such time limits and on such forms as the department may prescribe.

18. **Extensions of time.** The department may extend any of the time periods specified in subsections 4, 5, and 6 upon notification of the applicant by the department.

19. **Amendment of permits.** The department may, when the public interest requires or when necessary to ensure the accuracy of the permit, modify any condition or information contained in the permit to construct. Modification shall be made only upon the department's own motion and the procedure shall, at a minimum, conform to any requirements of federal and state law. In the event that the modification would ~~have a significant impact~~ be a major modification as defined in chapter 33-15-15, the department shall follow the procedures established in chapter 33-15-15. For those of concern to the public, the department will provide:

a. Reasonable notice to the public, in the area to be affected, of the opportunity for comment on the proposed modification, and the opportunity for a public hearing, upon request, as well as written public comment.

b. A minimum of a thirty-day period for written public comment, with the opportunity for a public hearing during that thirty-day period, upon request.

c. Consideration by the department of all comments received in its order for modification.

The department may require the submission of such maps, plans, specifications, emission information, and compliance schedules as it deems necessary prior to the issuance of an amendment. It is the intention of the department that this subsection shall apply only in those instances allowed by federal rules and regulations and only in those instances in which the granting of a variance pursuant to section 33-15-01-06 and enforcement of existing permit conditions are manifestly inappropriate.

History: Amended effective March 1, 1980; February 1, 1982; October 1, 1987; June 1, 1990; March 1, 1994; August 1, 1995; September 1, 1997; September 1, 1998; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03, 23-25-04, 23-25-04.1, 23-25-04.2
Law Implemented: NDCC 23-25-04, 23-25-04.1, 23-25-04.2

33-15-14-03. Minor source permit to operate.

1. **Permit to operate required.**

a. Except as provided in subdivisions c and d ~~of this subsection~~, no person may operate or cause the routine operation of an installation or source designated in section 33-15-14-01 without applying for and obtaining, in accordance with this section, a permit to operate. Application for a permit to operate a new installation or source must be made at least thirty days prior to startup of routine operation. Those sources that received a permit to construct under section 33-15-14-02, need only submit a thirty-day prior notice of proposed startup to satisfy the requirement to apply for a permit to operate under this subdivision.

b. No person may operate or cause the operation of an installation or source in violation of any permit to operate or any condition imposed upon a permit to operate or in violation of this article.

c. Sources that are subject to the title V permitting requirements of section 33-15-14-06 are exempt from the requirements of this section except during the transitional period from a minor source permit to operate to a title V permit to operate. Existing sources shall comply with all the requirements of this section until a title V permit to operate is issued. Fees for sources that meet the applicability requirements of section 33-15-14-06 shall be assessed based on section 33-15-23-04.

d. Sources that are exempt from the requirement to obtain a permit to construct under subsection 13 of section 33-15-14-02 are exempt from this section.

e. Sources which are subject to the title V permitting requirements in section 33-15-14-06 based solely on their potential to emit may apply for a federally enforceable minor source permit to operate which would limit their potential to emit to a level below the title V permit to operate applicability threshold.

f. Permits which are issued under this section which do not conform to the requirements of this section, including public participation under subdivision a of subsection 5 of section 33-15-14-03, and the requirements of any United States environmental protection agency regulations may be deemed not federally enforceable by the United States environmental protection agency.

g. General permits: The department may issue a general permit covering numerous similar sources. Any general permit shall comply with all requirements applicable to other minor source permits to operate and shall identify criteria by which sources may qualify for the general permit. To sources that qualify, the department shall grant the conditions and terms of the general permit. Sources that would qualify for a general permit must apply to the department for coverage under the terms of the general permit or apply for an individual minor source permit to operate. Without repeating the public participation procedures under subsection 5 of section 33-15-14-03, the department may grant a source's request for authorization to operate under a general permit.

2. **Application for permit to operate.**

a. Application for a permit to operate must be made by the owner or operator thereof on forms furnished by the department.

b. Each application for a permit to operate must be accompanied by such performance tests results, information, and records as may be required by the department to determine whether the requirements of this article will be met. Such information may also be required by the department at any time when the source is being operated to determine compliance with this article.

c. Each application must be signed by the applicant, which signature shall constitute an agreement that the applicant will assume responsibility for the operation of the installation or source in accordance with this article.

3. **Standards for granting permits to operate.** No permit to operate may be granted unless the applicant shows to the satisfaction of the department that the source is in compliance with this article.

4. **Performance testing.**

   a. Before a permit to operate is granted, the applicant, if required by the department, shall conduct performance tests in accordance with methods and procedures required by this article or methods and procedures approved by the department. Such tests must be made at the expense of the applicant. The department may monitor such tests and may also conduct performance tests.

   b. Emission tests or performance tests or both shall be conducted by the owner or operator of a facility and data reduced in accordance with the applicable procedure, limitations, standards, and test methods established by this article. Issuance of a minor source permit to operate is subject to the faithful completion of the test in accordance with this article.

   c. All dates and periods of trial operation for the purpose of performance or emission testing pursuant to a permit to operate must be approved in advance by the department. Trial operation shall cease if the department determines, on the basis of the test results, that continued operation will result in the violation of this article. Upon completion of any test conducted under a permit to construct, the department may order the cessation of the operation of the tested equipment or facility until such time as a permit to operate has been issued by the department.

   d. Upon review of the performance data resulting from any test, the department may require the installation of such additional control equipment as will bring the facility into compliance with this article.

   e. Nothing in this article may be construed to prevent the department from conducting any test upon its own initiative or from requiring the owner or operator to conduct any test at such time as the department may determine.

5. **Action on applications.**

   a. Public participation: This subdivision is applicable to only those sources which apply for a federally enforceable minor source permit to operate which limits their potential to emit an air contaminant. The department shall:

      (1) Within ninety days of receipt of a complete application:

(a) Make a preliminary determination concerning issuance of the permit to operate.

(b) Make available in at least one location in the county or counties in which the source is located, a copy of the proposed permit and copies of or a summary of the information considered in developing the permit.

(c) Publish notice to the public by prominent advertisement, in the region affected, of the opportunity for written comment on the proposed permit. The public notice must include the proposed location of the source.

(d) Deliver a copy of the proposed permit and public notice to ~~the chief executive of the city and county where the source is located; the regional land use planning agency; and~~ any state or federal land manager, or Indian governing body whose lands will be significantly affected by the source's emissions. For purposes of this subparagraph, lands will be considered to be significantly affected if the source is located within thirty-one and seven hundredths miles [50 kilometers] of such land.

(e) Provide a copy of the proposed permit, all information considered in the development of the permit and the public notice to the regional administrator of the United States environmental protection agency.

(2) Allow thirty days for public comment.

(3) Consider all public comments properly received, in making the final decision on the application.

(4) Allow the applicant to submit written responses to public comments received by the department. The applicant's responses must be submitted to the department within twenty days of the close of the public comment period.

(5) Take final action on the application within thirty days of the applicant's response to the public comments.

(6) Provide a copy of the final permit, if issued, to the applicant, the regional administrator of the United States environmental protection agency, and anyone who requests a copy.

b. For those sources not subject to public participation under subdivision a, the department shall act within thirty days after

receipt of an application for a permit to operate a new installation or source, and within thirty days after receipt of an application to operate an existing installation or source, and shall notify the applicant, in writing, of the approval, conditional approval, or denial of the application.

c. The department shall set forth in any notice of denial the reasons for denial. A denial must be without prejudice to the applicant's right to a hearing before the department or for filing a further application after revisions are made to meet objections specified as reasons for the denial.

6. **Permit to operate - Conditions.** The department may impose any reasonable conditions upon a permit to operate. All emission limitations, controls, and other requirements imposed by conditions on the permit to operate must be at least as stringent as any applicable limitation or requirement contained in this article. Permit to operate conditions may include:

   a. Sampling, testing, and monitoring of the facilities or ambient air or both.

   b. Trial operation and performance testing.

   c. Prevention and abatement of nuisance conditions caused by operation of the facility.

   d. Recordkeeping and reporting.

   e. Compliance with applicable rules and regulations in accordance with a compliance schedule.

   f. Limits on the hours of operation of a source or its processing rate, fuel usage, or production rate when necessary to assure compliance with this article.

7. **Suspension or revocation of permit to operate.**

   a. The department may suspend or revoke a permit to operate for violation of this article, violations of a permit condition, or failure to respond to a notice of violation or any order issued pursuant to this article.

   b. Suspension or revocation of a permit to operate shall become final ten days after serving notice on the holder of the permit.

   c. A permit to operate which has been revoked pursuant to this article must be surrendered forthwith to the department.

d. No person may operate or cause the operation of an installation or source if the department denies or revokes a permit to operate.

8. **Transfer of permit to operate.** The holder of a permit to operate may not transfer it without the prior approval of the department.

9. **Renewal of permit to operate.**

a. Every permit to operate issued by the department after February 9, 1976, shall become void upon the fifth anniversary of its issuance. Applications for renewal of such permits must be submitted ninety days prior to such anniversary date. The department shall approve or disapprove such application within ninety days. If a source submits a complete application for a permit renewal at least ninety days prior to the expiration date, the source's failure to have a minor source permit to operate is not a violation of this section until the department takes final action on the renewal application.

b. The department may amend permits issued prior to February 9, 1976, so as to provide for voidance upon the fifth anniversary of its issuance.

10. **[Reserved]**

11. ~~**Performance and emission testing.**~~ **[Reserved]**

~~a. Emission tests or performance tests or both shall be conducted by the owner or operator of a facility and data reduced in accordance with the applicable procedure, limitations, standards, and test methods established by this article. Issuance of a minor source permit to operate is subject to the faithful completion of the test in accordance with this article.~~

~~b. All dates and periods of trial operation for the purpose of performance or emission testing pursuant to a permit to operate must be approved in advance by the department. Trial operation shall cease if the department determines, on the basis of the test results, that continued operation will result in the violation of this article. Upon completion of any test conducted under a permit to construct, the department may order the cessation of the operation of the tested equipment or facility until such time as a permit to operate has been issued by the department.~~

~~c. Upon review of the performance data resulting from any test, the department may require the installation of such additional control equipment as will bring the facility into compliance with this article.~~

~~d. Nothing in this article may be construed to prevent the department from conducting any test upon its own initiative or from requiring~~

~~the owner or operator to conduct any test at such time as the department may determine.~~

12. **Responsibility to comply.**

    a. Possession of a minor source permit to operate does not relieve any person of the responsibility to comply with this article.

    b. The exemption of any stationary source from the requirements to obtain a minor source permit to operate does not relieve the owner or operator of such source of the responsibility to comply with any other applicable portions of this article.

13. **Portable sources.** Sources which are designed to be portable and which are operated at temporary jobsites across the state may not be considered a new source by virtue of location changes. One application for a permit to operate any portable source may be filed in accordance with this chapter, and subsequent applications are not required for each temporary jobsite. The permit to operate issued by the department shall be conditioned by such specific requirements as the department deems appropriate to carry out the provisions of sections 33-15-01-07 and 33-15-01-15.

14. **Registration of exempted stationary sources.** The department may require that the owner or operator of any stationary source exempted from the requirement to obtain a minor source permit to operate to register the source with the department within such time limits and on such forms as the department may prescribe.

15. **Extensions of time.** The department may extend any of the time periods specified in this section upon notification of the applicant by the department.

16. **Amendment of permits.** When the public interest requires or when necessary to ensure the accuracy of the permit, the department may modify any condition or information contained in a minor source permit to operate. Modification shall be made only upon the department's own motion and the procedure shall, at a minimum, conform to any requirements of federal and state law. In the event that the modification would ~~have a significant impact~~ <u>be a major modification</u> as defined in chapter 33-15-15, the department shall follow the procedures established in chapter 33-15-15. For those of concern to the public, or modify a condition which limits the potential to emit of a source which possesses a federally enforceable permit, the department will provide:

    a. Reasonable notice to the public, in the area to be affected, of the opportunity for comment on the proposed modification and the opportunity for a public hearing, upon request, as well as written public comment.

b. A minimum of a thirty-day period for written public comment with the opportunity for a public hearing during that thirty-day period, upon request.

c. Consideration by the department of all comments received.

The department may require the submission of such maps, plans, specifications, emission information, and compliance schedules as it deems necessary prior to the issuance of an amendment. It is the intention of the department that this subsection shall apply only in those instances allowed by federal rules and regulations and only in those instances in which the granting of a variance pursuant to section 33-15-01-06 and enforcement of existing permit conditions are manifestly inappropriate.

History: Amended effective February 1, 1982; October 1, 1987; March 1, 1994; August 1, 1995; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03, 23-25-04.1, 23-25-04.2
Law Implemented: NDCC 23-25-03, 23-25-04.1, 23-25-04.2

33-15-14-06. Title V permit to operate.

1. **Definitions.** For purposes of this section:

a. "Affected source" means any source that includes one or more affected units.

b. "Affected state" means any state that is contiguous to North Dakota whose air quality may be affected by a source subject to a proposed title V permit, permit modification, or permit renewal or which is within fifty miles [80.47 kilometers] of the permitted source.

c. "Affected unit" means a unit that is subject to any acid rain emissions reduction requirement or acid rain emissions limitation under title VI of the Federal Clean Air Act.

d. "Applicable requirement" means all of the following as they apply to emissions units at a source that is subject to requirements of this section (including requirements that have been promulgated or approved by the United States environmental protection agency through rulemaking at the time of issuance but have future-effective compliance dates):

(1) Any standard or other requirement provided for in the North Dakota state implementation plan approved or promulgated by the United States environmental protection agency through rulemaking under title I of the Federal Clean Air Act that implements the relevant requirements of the Federal Clean Air Act, including any revisions to that plan.

(2) Any term or condition of any permit to construct issued pursuant to this chapter.

(3) Any standard or other requirement under section 111 including section 111(d) of the Federal Clean Air Act.

(4) Any standard or other requirement under section 112 of the Federal Clean Air Act including any requirement concerning accident prevention under section 112(r)(7) of the Federal Clean Air Act.

(5) Any standard or other requirement of the acid rain program under title IV of the Federal Clean Air Act.

(6) Any requirements established pursuant to section 504(b) or section 114(a)(3) of the Federal Clean Air Act.

(7) Any standard or other requirement governing solid waste incineration, under section 129 of the Federal Clean Air Act.

(8) Any standard or other requirement for consumer and commercial products, under section 183(e) of the Federal Clean Air Act.

(9) Any standard or other requirement for tank vessels under section 183(f) of the Federal Clean Air Act.

(10) Any standard or other requirement of the program to control air pollution from outer continental shelf sources, under section 328 of the Federal Clean Air Act.

(11) Any standard or other requirement of the regulations promulgated to protect stratospheric ozone under title VI of the Federal Clean Air Act, unless the administrator of the United States environmental protection agency has determined that such requirements need not be contained in a title V permit.

(12) Any national ambient air quality standard or increment or visibility requirement under part C of title I of the Federal Clean Air Act, but only as it would apply to temporary sources permitted pursuant to section 504(e) of the Federal Clean Air Act.

e. "Designated representative" means a responsible natural person authorized by the owners and operators of an affected source and of all affected units at the source, as evidenced by a certificate of representation submitted in accordance with subpart B of 40 CFR 72, to represent and legally bind each owner and operator, as a

matter of federal law, in matters pertaining to the acid rain program. Whenever the term "responsible official" is used in this section, or in any other regulations implementing title V of the Federal Clean Air Act, it shall be deemed to refer to the "designated representative" with regard to all matters under the acid rain program.

f. "Draft permit" means the version of a permit for which the department offers public participation or affected state review.

g. "Emergency" means any situation arising from sudden and reasonably unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the title V permit to operate, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventive maintenance, careless or improper operation, or operator error.

h. "Emissions allowable under the permit" means a federally enforceable permit term or condition determined at issuance to be required by an applicable requirement that establishes an emissions limit (including a work practice standard) or a federally enforceable emissions cap that the source has assumed to avoid an applicable requirement to which the source would otherwise be subject.

i. "Emissions unit" means any part or activity of a stationary source that emits or has the potential to emit any regulated air contaminant or any contaminant listed under section 112(b) of the Federal Clean Air Act. This term does not alter or affect the definition of unit for purposes of title IV of the Federal Clean Air Act.

j. "Environmental protection agency" or the "administrator" means the administrator of the United States environmental protection agency or the administrator's designee.

k. "Federal Clean Air Act" means the Federal Clean Air Act, as amended [42 U.S.C. 7401 et seq.].

l. "Final permit" means the version of a title V permit issued by the department that has completed all review procedures required in this section.

m. "Fugitive emissions" are those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening.

n. "General permit" means a title V permit to operate that meets the requirements of subdivision d of subsection 5.

o. "Major source" means any stationary source (or any group of stationary sources that are located on one or more contiguous or adjacent properties, and are under common control of the same person (or persons under common control)) belonging to a single major industrial grouping and that are described in paragraph 1 or 2. For the purposes of defining "major source", a stationary source or group of stationary sources shall be considered part of a single industrial grouping if all of the contaminant emitting activities at such source or group of sources on contiguous or adjacent properties belong to the same major group (i.e., all have the same two-digit code) as described in the standard industrial classification manual, 1987.

(1) A major source under section 112 of the Federal Clean Air Act, which is defined as:

(a) For contaminants other than radionuclides, any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, in the aggregate, ten tons [9.07 metric tons] per year (tpy) or more of any hazardous air contaminant which has been listed pursuant to section 112(b) of the Federal Clean Air Act, twenty-five tons [22.67 metric tons] per year or more of any combination of such hazardous air contaminants, or such lesser quantity as the administrator of the United States environmental protection agency may establish by rule. Notwithstanding the preceding sentence, emissions from any oil or gas exploration or production well (with its associated equipment) and emissions from any pipeline compressor pump station shall not be aggregated with emissions from other similar units, whether or not such units are in a contiguous area or under common control, to determine whether such units or stations are major sources.

(b) For radionuclides, "major source" shall have the meaning specified by the administrator of the United States environmental protection agency by rule.

(2) A major stationary source of air contaminants, that directly emits or has the potential to emit, one hundred tons [90.68 metric tons] per year or more of any air contaminant (including any major source of fugitive emissions of any such contaminant, as determined by rule by the administrator of the United States environmental protection agency).

The fugitive emissions of a stationary source shall not be considered in determining whether it is a major stationary source for the purposes of this section, unless the source belongs to one of the following categories of stationary source:

(a) Coal cleaning plants (with thermal dryers).

(b) Kraft pulp mills.

(c) Portland cement plants.

(d) Primary zinc smelters.

(e) Iron and steel mills.

(f) Primary aluminum ore reduction plants.

(g) Primary copper smelters.

(h) Municipal incinerators capable of charging more than two hundred fifty tons [226.80 metric tons] of refuse per day.

(i) Hydrofluoric, sulfuric, or nitric acid plants.

(j) Petroleum refineries.

(k) Lime plants.

(l) Phosphate rock processing plants.

(m) Coke oven batteries.

(n) Sulfur recovery plants.

(o) Carbon black plants (furnace process).

(p) Primary lead smelters.

(q) Fuel conversion plants.

(r) Sintering plants.

(s) Secondary metal production plants.

(t) Chemical process plants.

(u) Fossil-fuel boilers (or combination thereof) totaling more than two hundred fifty million British thermal units per hour heat input.

(v) Petroleum storage and transfer units with a total storage capacity exceeding three hundred thousand barrels.

(w) Taconite ore processing plants.

(x) Glass fiber processing plants.

(y) Charcoal production plants.

(z) Fossil-fuel-fired steam electric plants of more than two hundred fifty million British thermal units per hour heat input.

(aa) ~~All~~ Any other stationary source ~~categories~~ category which as of August 7, 1980, is being regulated ~~by a standard promulgated~~ under section 111 or 112 of the Federal Clean Air Act~~, but only with respect to those air contaminants that have been regulated for that category~~.

p. "Permit modification" means a revision to a title V permit that meets the requirements of subdivision e of subsection 6.

q. "Permit program costs" means all reasonable (direct and indirect) costs required to develop and administer a permit program, under this section (whether such costs are incurred by the department or other state or local agencies that do not issue permits directly, but that support permit issuance or administration).

r. "Permit revision" means any permit modification or administrative permit amendment.

s. "Potential to emit" means the maximum capacity of a stationary source to emit any air contaminant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air contaminant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation is enforceable by the administrator of the United States environmental protection agency and the department.

t. "Proposed permit" means the version of a permit that the department proposes to issue and forwards to the administrator of the United States environmental protection agency for review.

u. "Regulated air contaminant" means the following:

(1) Nitrogen oxides or any volatile organic compounds.

(2) Any contaminant for which a national ambient air quality standard has been promulgated.

(3) Any contaminant that is subject to any standard promulgated under section 111 of the Federal Clean Air Act.

(4) Any class I or II substance subject to a standard promulgated under or established by title VI of the Federal Clean Air Act.

(5) Any contaminant subject to a standard promulgated under section 112 or other requirements established under section 112 of the Federal Clean Air Act, including sections 112(g), (j), and (r) of the Federal Clean Air Act, including the following:

(a) Any contaminant subject to requirements under section 112(j) of the Federal Clean Air Act. If the administrator fails to promulgate a standard by the date established pursuant to section 112(e) of the Federal Clean Air Act, any contaminant for which a subject source would be major shall be considered to be regulated on the date eighteen months after the applicable date established pursuant to section 112(e) of the Federal Clean Air Act; and

(b) Any contaminant for which the requirements of section 112(g)(2) of the Federal Clean Air Act have been met, but only with respect to the individual source subject to section 112(g)(2) of the Federal Clean Air Act requirement.

v. "Regulated contaminant" for fee calculation, which is used only for chapter 33-15-23, means any "regulated air contaminant" except the following:

(1) Carbon monoxide.

(2) Any contaminant that is a regulated air contaminant solely because it is a class I or II substance subject to a standard promulgated under or established by title VI of the Federal Clean Air Act.

(3) Any contaminant that is a regulated air contaminant solely because it is subject to a standard or regulation under section 112(r) of the Federal Clean Air Act.

w. "Renewal" means the process by which a permit is reissued at the end of its term.

x. "Responsible official" means one of the following:

(1) For a corporation: a president, secretary, treasurer, or vice president of the corporation in charge of a principal business function, or any other person who performs similar policy or decisionmaking functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(a) The facilities employ more than two hundred fifty persons or have gross annual sales or expenditures exceeding twenty-five million dollars (in second quarter 1980 dollars).

(b) The delegation of authority to such representatives is approved in advance by the department.

(2) For a partnership or sole proprietorship: a general partner or the proprietor, respectively.

(3) For a municipality, state, federal, or other public agency: either a principal executive officer or ranking elected official. For the purposes of this section, a principal executive officer of a federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a regional administrator of the United States environmental protection agency).

(4) For affected sources:

(a) The designated representative insofar as actions, standards, requirements, or prohibitions under title IV of the Federal Clean Air Act or the regulations promulgated thereunder are concerned.

(b) The designated representative for any other purposes under this section.

y. "Section 502(b)(10) changes" are changes that contravene an express permit term. Such changes do not include changes that would violate applicable requirements or contravene federally enforceable permit terms and conditions that are monitoring (including test methods), recordkeeping, reporting, or compliance certification requirements.

z. "Stationary source" means any building, structure, facility, or installation that emits or may emit any regulated air contaminant or any contaminant listed under section 112(b) of the Federal Clean Air Act.

aa. "Title V permit to operate or permit" (unless the context suggests otherwise) means any permit or group of permits covering a source that is subject to this section that is issued, renewed, amended, or revised pursuant to this section.

bb. "Title V source" means any source subject to the permitting requirements of this section, as provided in subsection 2.

2. **Applicability.**

a. This section is applicable to the following sources:

(1) Any major source.

(2) Any source, including an area source, subject to a standard, limitation, or other requirement under section 111 of the Federal Clean Air Act.

(3) Any source, including an area source, subject to a standard or other requirement under section 112 of the Federal Clean Air Act, except that a source is not required to obtain a permit solely because it is subject to regulations or requirements under section 112(r) of the Federal Clean Air Act.

(4) Any affected source.

(5) Any source in a source category designated by the administrator of the United States environmental protection agency.

b. The following source categories are exempt from the requirements of this section:

(1) All sources listed in subdivision a that are not major sources, affected sources, or solid waste incineration units required to obtain a permit pursuant to section 129(e) of the Federal Clean Air Act, are exempt from the obligation to obtain a title V permit until such time as the administrator of the United States environmental protection agency completes a rulemaking to determine how the program should be structured for nonmajor sources and the appropriateness of any permanent exemptions.

(2) In the case of nonmajor sources subject to a standard or other requirement under either section 111 or 112 of the Federal Clean Air Act after July 21, 1992, those the administrator of the United States environmental protection agency determines to be exempt from the requirement to obtain a title V source permit at the time that the new standard is promulgated.

(3) Any source listed as exempt from the requirement to obtain a permit under this section may opt to apply for a title V permit. Sources that are exempted by paragraphs 1 and 2 and which do not opt to apply for a title V permit to operate are subject to the requirements of section 33-15-14-03.

(4) The following source categories are exempted from the obligation to obtain a permit under this section.

(a) All sources and source categories that would be required to obtain a permit solely because they are subject to 40 CFR 60, subpart AAA - standards of performance for new residential wood heaters.

(b) All sources and source categories that would be required to obtain a permit solely because they are subject to 40 CFR 61, subpart M - national emission standard for hazardous air pollutants for asbestos, section 61.145, standard for demolition and renovation.

c. For major sources, the department will include in the permit all applicable requirements for all relevant emissions units in the major source.

For any nonmajor source subject to the requirements of this section, the department will include in the permit all applicable requirements applicable to the emissions units that cause the source to be subject to this section.

d. Fugitive emissions from a source subject to the requirements of this section shall be included in the permit application and the permit in the same manner as stack emissions, regardless of whether the source category in question is included in the list of sources contained in the definition of major source.

3. **Scope.** Nothing within this section shall relieve the owner or operator of a source of the requirement to obtain a permit to construct under section 33-15-14-02 or to comply with any other applicable standard or requirement of this article.

4. **Permit applications.**

a. Duty to apply. For each title V source, the owner or operator shall submit a timely and complete permit application in accordance with this subdivision.

(1) Timely application.

(a) A timely application for a source applying for a title V permit for the first time is one that is submitted within one year of ~~the United States environmental protection agency approval of this rule or in accordance with the following schedule, whichever is earlier:~~ the source becoming subject to this section.

~~[1] The following designated air contaminant sources shall submit their initial application by May 1, 1995.~~

~~[a] Crude oil and natural gas production facilities.~~

~~[b] Natural gas processing facilities.~~

~~[c] Internal combustion engines used for natural gas transmission or distribution.~~

~~[d] Stationary gas turbines used for natural gas transmission or distribution.~~

~~[2] Except as provided in subparagraphs b, c, and d, all other applications shall be submitted by August 7, 1996.~~

(b) Title V sources required to meet the requirements under section 112(g) of the Federal Clean Air Act, or to have a permit to construct under section 33-15-14-02, shall file a complete application to obtain the title V permit or permit revision within twelve months after commencing operation. Where an existing title V permit would prohibit such construction or change in operation, the source must obtain a permit revision before commencing operation.

(c) For purposes of permit renewal, a timely application is one that is submitted at least six months, but not more than eighteen months, prior to the date of permit expiration.

~~(d) Applications for initial phase II acid rain permits shall be submitted to the department by January 1, 1996,~~

~~for sulfur dioxide, and by January 1, 1998, for nitrogen oxides.~~

(2) Complete application. To be deemed complete, an application must provide all information required pursuant to subdivision c, except that applications for a permit revision need supply such information only if it is related to the proposed change. Information required under subdivision c must be sufficient to evaluate the subject source and its application and to determine all applicable requirements. A responsible official must certify the submitted information consistent with subdivision d. Unless the department determines that an application is not complete within sixty days of receipt of the application, such application shall be deemed to be complete, except as otherwise provided in paragraph 3 of subdivision a of subsection 6. If, while processing an application that has been determined or deemed to be complete, the department determines that additional information is necessary to evaluate or take final action on that application, it may request such information in writing and set a reasonable deadline for a response. The source's ability to operate without a permit, as set forth in subdivision b of subsection 6, shall be in effect from the date the application is determined or deemed to be complete until the final permit is issued, provided that the applicant submits any requested additional information by the deadline specified by the department.

(3) Confidential information. If a source has submitted information to the department under a claim of confidentiality, the source must also submit a copy of such information directly to the administrator of the United States environmental protection agency when directed to do so by the department.

b. Duty to supplement or correct application. Any applicant who fails to submit any relevant facts or who has submitted incorrect information in a permit application shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary facts or corrected information. In addition, an applicant shall provide additional information as necessary to address any requirements that become applicable to the source after the date it filed a complete application but prior to release of a draft permit.

c. Standard application form and required information. All applications for a title V permit to operate shall be made on forms supplied by the department. Information as described below for each emissions unit at a title V source shall be included in the

application. ~~Emissions~~ Detailed information for emissions units or activities that have the potential to emit less than the following quantities of air contaminants (insignificant units or activities) need not be included in permit applications:

Particulate: 2 tons [1.81 metric tons] per year

Inhalable particulate: 2 tons [1.81 metric tons] per year

Sulfur dioxide: 2 tons [1.81 metric tons] per year

Hydrogen sulfide: 2 tons [1.81 metric tons] per year

Carbon monoxide: 2 tons [1.81 metric tons] per year

Nitrogen oxides: 2 tons [1.81 metric tons] per year

Ozone: 2 tons [1.81 metric tons] per year

Reduced sulfur compounds: 2 tons [1.81 metric tons] per year

Volatile organic compounds: 2 tons [1.81 metric tons]

All other regulated contaminants including those in section 112(b) of the Federal Clean Air Act: 0.5 tons [0.45 metric tons] per year.

Where a contaminant could be placed in more than one category, the smallest emission level applies.

However, for ~~exempted~~ insignificant activities or emissions units, a list of such activities or units must be included in the application. An applicant may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate the fee amount required under section 33-15-23-04. The application, shall, as a minimum, include the elements specified below:

(1) Identifying information, including company name and address (or plant name and address if different from the company name), owner's name and agent, and telephone number and names of plant site manager or contact.

(2) A description of the source's processes and products (by Standard Industrial Classification Code) including any associated with each alternate scenario identified by the source.

(3) The following emissions-related information:

(a) All emissions of contaminants for which the source is major, and all emissions of regulated air contaminants. A permit application shall describe all emissions of regulated air contaminants emitted from any emissions unit, except ~~where~~ when such units are exempted under this subdivision.

(b) Identification and description of all points of emissions described in subparagraph a in sufficient detail to establish the basis for fees and applicability of requirements of the Federal Clean Air Act and this article.

(c) Emissions rates in tons per year, in terms of the applicable standard, and terms that are necessary to establish compliance with the applicable compliance method.

(d) Fuels, fuel use, raw materials, production rates, and operating schedules.

(e) Identification and description of air pollution control equipment and compliance monitoring devices or activities.

(f) Limitations on source operation affecting emissions or any work practice standards, ~~where~~ when applicable, for all regulated contaminants.

(g) Other information required by any applicable requirement including information related to stack height limitations developed pursuant to chapter 33-15-18.

(h) Calculations on which the information in subparagraphs a through g is based.

(4) The following air pollution control requirements:

(a) Citation and description of all applicable requirements; and

(b) Description of or reference to any applicable test method for determining compliance with each applicable requirement.

(5) Other specific information that may be necessary to implement and enforce other applicable requirements of

the Federal Clean Air Act or of this article or to determine the applicability of such requirements.

(6) An explanation of any proposed exemptions from otherwise applicable requirements.

(7) Information that the department determines to be necessary to define alternative operating scenarios identified by the source or to define permit terms and conditions.

(8) A compliance plan for all title V sources that contains all the following:

(a) A description of the compliance status of the source with respect to all applicable requirements.

(b) A description as follows:

[1] For applicable requirements with which the source is in compliance, a statement that the source will continue to comply with such requirements.

[2] For applicable requirements that will become effective during the permit term, a statement that the source will meet such requirements on a timely basis.

[3] For requirements for which the source is not in compliance at the time of permit issuance, a narrative description of how the source will achieve compliance with such requirements.

(c) A compliance schedule as follows:

[1] For applicable requirements with which the source is in compliance, a statement that the source will continue to comply with such requirements.

[2] For applicable requirements that will become effective during the permit term, a statement that the source will meet such requirements on a timely basis. A statement that the source will meet in a timely manner applicable requirements that become effective during the permit term shall satisfy this provision, unless a more detailed schedule is expressly required by the applicable requirement.

[3] A schedule of compliance for sources that are not in compliance with all applicable requirements at the time of permit issuance. Such a schedule shall include a schedule of remedial measures, including an enforceable sequence of actions with milestones, leading to compliance with any applicable requirements for which the source will be in noncompliance at the time of permit issuance. This compliance schedule shall resemble and be at least as stringent as that contained in any judicial consent decree or administrative order to which the source is subject. Any such schedule of compliance shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based.

(d) A schedule for submission of certified progress reports no less frequently than every six months for sources required to have a schedule of compliance to remedy a violation.

(e) The compliance plan content requirements specified in this paragraph shall apply and be included in the acid rain portion of a compliance plan for an affected source, except as specifically superseded by regulations promulgated under title IV of the Federal Clean Air Act with regard to the schedule and method or methods the source will use to achieve compliance with the acid rain emissions limitations.

(9) Requirements for compliance certification, including the following:

(a) A certification of compliance with all applicable requirements by a responsible official consistent with subdivision d and section 114(a)(3) of the Federal Clean Air Act;

(b) A statement of methods used for determining compliance, including a description of monitoring, recordkeeping, and reporting requirements and test methods;

(c) A schedule for submission of compliance certifications during the permit term, to be submitted annually, or more frequently if specified by the underlying applicable requirement; and

(d) A statement indicating the source's compliance status with any applicable enhanced monitoring and compliance certification requirements of the Federal Clean Air Act.

(10) The use of nationally standardized forms for acid rain portions of permit applications and compliance plans, as required by regulations promulgated under title IV of the Federal Clean Air Act.

d. Any application form, report, or compliance certification submitted pursuant to these rules shall contain certification by a responsible official of truth, accuracy, and completeness. This certification and any other certification required under this section shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

5. **Permit content.**

a. Standard permit requirements. Each permit issued under this section shall include, as a minimum, the following elements:

(1) Emissions limitations and standards, including those operational requirements and limitations that assure compliance with all applicable requirements at the time of permit issuance.

(a) The permit must specify and reference the origin of and authority for each term or condition, and identify any difference in form as compared to the applicable requirement upon which the term or condition is based.

(b) The permit must state that, ~~where~~ if an applicable requirement of the Federal Clean Air Act is more stringent than an applicable requirement of regulations promulgated under title IV of the Federal Clean Air Act, both provisions shall be incorporated into the permit and shall be enforceable by the administrator of the United States environmental protection agency and the department.

(c) ~~Where~~ If the state implementation plan allows a determination of an alternative emissions limit at a title V source, equivalent to that contained in the plan, to be made in the permit issuance, renewal, or significant modification process, and the department elects to use such process, any permit containing such equivalency determination shall contain provisions to ensure that

any resulting emissions limit has been demonstrated to be quantifiable, accountable, enforceable, and based on replicable procedures.

(2) Permit duration. Each title V permit to operate shall expire upon the fifth anniversary of its issuance.

(3) Monitoring and related recordkeeping and reporting requirements.

(a) Each permit shall contain the following requirements with respect to monitoring:

[1] All monitoring and analysis procedures or test methods required under applicable monitoring and testing requirements, including subsection 10 and any procedures and methods promulgated pursuant to sections 504(b) or 114(a)(3) of the Federal Clean Air Act. If more than one monitoring or testing requirement applies, the permit may specify a streamlined set of monitoring or testing provisions provided the specified monitoring or testing is adequate to assure compliance at least to the same extent as the monitoring or testing applicable requirements that are not included in the permit as a result of such streamlining;

[2] ~~Where~~ If the applicable requirement does not require periodic testing or instrumental or noninstrumental monitoring (which may consist of recordkeeping designed to serve as monitoring), periodic monitoring sufficient to yield reliable data from the relevant time period that are representative of the source's compliance with the permit, as reported pursuant to subparagraph c. Such monitoring requirements shall assure use of terms, test methods, units, averaging periods, and other statistical conventions consistent with the applicable requirement. Recordkeeping provisions may be sufficient to meet the requirements of this item; and

[3] As necessary, requirements concerning the use, maintenance, and, ~~where~~ if appropriate, installation of monitoring equipment or methods.

(b) With respect to recordkeeping, the permit shall incorporate all applicable recordkeeping requirements and require, ~~where~~ if applicable, the following:

[1] Records of required monitoring information that include the following:

[a] The date, place as defined in the permit, and time of sampling or measurements;

[b] The dates analyses were performed;

[c] The company or entity that performed the analyses;

[d] The analytical techniques or methods used;

[e] The results of such analyses; and

[f] The operating conditions as existing at the time of sampling or measurement;

[2] Retention of records of all required monitoring data and support information for a period of at least five years from the date of the monitoring sample, measurement, report, or application. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by the permit.

(c) With respect to reporting, the permit shall incorporate all applicable reporting requirements and require the following:

[1] Submittal of reports of any required monitoring at least every six months. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official consistent with subdivision d of subsection 4.

[2] Prompt reporting of deviations from permit requirements, including those attributable to upset conditions as defined in the permit, the probable cause of such deviations, and any corrective actions or preventive measures taken. The department shall define "prompt" in the

permit consistent with chapter 33-15-01 and the applicable requirements.

(4) A permit condition prohibiting emissions exceeding any allowances that the source lawfully holds under title IV of the Federal Clean Air Act or the regulations promulgated thereunder.

(a) No permit revision shall be required for increases in emissions that are authorized by allowances acquired pursuant to title IV of the Federal Clean Air Act, or the regulations promulgated thereunder, provided that such increases do not require a permit revision under any other applicable requirement.

(b) No limit shall be placed on the number of allowances held by the source. The source may not, however, use allowances as a defense to noncompliance with any other applicable requirement.

(c) Any such allowance shall be accounted for according to the procedures established in regulations promulgated under title IV of the Federal Clean Air Act.

(5) A severability clause to ensure the continued validity of the various permit requirements in the event of a challenge to any portions of the permit.

(6) Provisions stating the following:

(a) The permittee must comply with all conditions of the title V permit. Any permit noncompliance constitutes a violation of the Federal Clean Air Act and this article and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

(b) It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

(c) The permit may be modified, revoked, reopened, and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.

(d) The permit does not convey any property rights of any sort, or any exclusive privilege.

(e) The permittee must furnish to the department, within a reasonable time, any information that the department may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee must also furnish to the department copies of records required to be kept by the permit or, for information claimed to be confidential, the permittee must also furnish such records directly to the administrator of the United States environmental protection agency along with a claim of confidentiality.

(7) A provision to ensure that the source pays fees to the department consistent with the fee schedule in chapter 33-15-23.

(8) Emissions trading. No permit revision shall be required, under any approved economic incentives, marketable permits, emissions trading and other similar programs or processes for changes that are provided for in the permit and the state implementation plan.

(9) Terms and conditions for reasonably anticipated operating scenarios identified by the source in its application as approved by the department. Such terms and conditions:

(a) Shall require the source, contemporaneously with making a change from one operating scenario to another, to record in a log at the permitted facility a record of the scenario under which it is operating;

(b) Shall extend the permit shield described in subdivision f to all terms and conditions under each such operating scenario; and

(c) Must ensure that the terms and conditions of each such alternative scenario meet all applicable requirements and the requirements of this section.

(10) Terms and conditions, if the permit applicant requests them, for the trading of emissions increases and decreases in the permitted facility, to the extent that the applicable requirements, including the state implementation plan, provide for trading such increases and decreases without a

case-by-case approval of each emissions trade. Such terms and conditions:

(a) Shall include all terms required under subdivisions a and c to determine compliance;

(b) Shall extend the permit shield described in subdivision f to all terms and conditions that allow such increases and decreases in emissions; and

(c) Must meet all applicable requirements and requirements of this section.

(11) If a permit applicant requests it, the department shall issue permits that contain terms and conditions, including all terms required under subdivisions a and c to determine compliance, allowing for the trading of emissions increases and decreases in the permitted facility solely for the purpose of complying with a federally enforceable emissions cap that is established in the permit independent of otherwise applicable requirements provided the changes in emissions are not modifications under title I of the Federal Clean Air Act and the changes do not exceed the emissions allowable under the permit. The permit applicant shall include in its application proposed replicable procedures and permit terms that ensure the emissions trades are quantifiable and enforceable. The department shall not be required to include in the emissions trading provisions any emissions units for which emissions are not quantifiable or for which there are no replicable procedures to enforce the emissions trades. The permit shall also require compliance with all applicable requirements. The permittee shall supply written notification at least seven days prior to the change to the department and the administrator of the United States environmental protection agency and shall state when the change will occur and shall describe the changes in emissions that will result and how these increases and decreases in emissions will comply with the terms and conditions of the permit. The permit shield described in subdivision f shall extend to terms and conditions that allow such increases and decreases in emissions.

b. Federally enforceable requirements.

(1) All terms and conditions in a title V permit, including any provisions designed to limit a source's potential to emit, are enforceable by the administrator of the United States environmental protection agency and citizens under the Federal Clean Air Act.

(2) Notwithstanding paragraph 1, the department shall specifically designate as not being federally enforceable under the Federal Clean Air Act any terms and conditions included in the permit that are not required under the Federal Clean Air Act or under any of its applicable requirements. Terms and conditions so designated are not subject to the requirements of subsections 6 and 7, or of this subsection, other than those contained in this subdivision.

c. Compliance requirements. All title V permits shall contain the following elements with respect to compliance:

(1) Consistent with paragraph 3 of subdivision a, compliance certification, testing, monitoring, reporting, and recordkeeping requirements sufficient to assure compliance with the terms and conditions of the permit. Any document, including reports, required by a title V permit shall contain a certification by a responsible official that meets the requirements of subdivision d of subsection 4.

(2) Inspection and entry requirements that require that, upon presentation of credentials and other documents as may be required by law, the permittee shall allow the department or an authorized representative to perform the following:

(a) Enter upon the permittee's premises where a title V source is located or emissions-related activity is conducted, or where records must be kept under the conditions of the permit;

(b) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;

(c) Inspect at reasonable times any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit; and

(d) As authorized by the Federal Clean Air Act and this article, sample or monitor at reasonable times substances or parameters for the purpose of assuring compliance with the permit or applicable requirements.

(3) A schedule of compliance consistent with paragraph 8 of subdivision c of subsection 4.

(4) Progress reports consistent with an applicable schedule of compliance and paragraph 8 of subdivision c of subsection 4

to be submitted at least semiannually, or at a more frequent period if specified in the applicable requirement or by the department. Such progress reports shall contain the following:

(a) Dates for achieving the activities, milestones, or compliance required in the schedule of compliance, and dates when such activities, milestones, or compliance were achieved; and

(b) An explanation of why any dates in the schedule of compliance were not or will not be met, and any preventive or corrective measures adopted.

(5) Requirements for compliance certification with terms and conditions contained in the permit, including emissions limitations, standards, or work practices. Permits shall include each of the following:

(a) The frequency, which is annually or such more frequent periods as specified in the applicable requirement or by the department, of submissions of compliance certifications;

(b) In accordance with paragraph 3 of subdivision a, a means for monitoring the compliance of the source with its emissions limitations, standards, and work practices. The means for monitoring shall be contained in applicable requirements or United States environmental protection agency guidance;

(c) A requirement that the compliance certification include all of the following (provided that the identification of applicable information may cross-reference the permit or previous reports, as applicable):

[1] The identification of each term or condition of the permit that is the basis of the certification;

[2] The identification of the methods or other means used by the owner or operator for determining the compliance status with each term and condition during the certification period, and whether such methods or other means provide continuous or intermittent data. Such methods and other means shall include, at a minimum, the methods and means required under paragraph 3 of subdivision a. If necessary, the owner or operator also shall identify any other material information

that must be included in the certification to comply with section 113(c)(2) of the Federal Clean Air Act, which prohibits knowingly making a false certification or omitting material information;

[3] The status of compliance with the terms and conditions of the permit for the period covered by the certification, based on the method or means designated in item 2. The certification shall identify each deviation and take it into account in the compliance certification. The certification shall also identify as possible exceptions to compliance any periods during which compliance is required and in which an excursion or exceedance as defined under subsection 10 occurred; and

[4] Such other facts as the department may require to determine the compliance status of the source;

(d) A requirement that all compliance certifications be submitted to the administrator of the United States environmental protection agency as well as to the department; and

(e) Such additional requirements as may be specified pursuant to sections 114(a)(3) and 504(b) of the Federal Clean Air Act.

(6) Such other provisions as the department may require.

d. General permits.

(1) The department may, after notice and opportunity for public participation provided under subdivision h of subsection 6, issue a general permit covering numerous similar sources. Any general permit shall comply with all requirements applicable to other title V permits and shall identify criteria by which sources may qualify for the general permit. To sources that qualify, the department shall grant the conditions and terms of the general permit. Notwithstanding the shield provisions of subdivision f, the source shall be subject to enforcement action for operation without a title V permit to operate if the source is later determined not to qualify for the conditions and terms of the general permit. General permits shall not be authorized for affected sources under the acid rain program unless otherwise provided in regulations promulgated under title IV of the Federal Clean Air Act. The

department is not required to issue a general permit in lieu of individual title V permits.

(2) Title V sources that would qualify for a general permit must apply to the department for coverage under the terms of the general permit or must apply for a title V permit to operate consistent with subsection 4. The department may, in the general permit, provide for applications which deviate from the requirements of subsection 4, provided that such applications meet the requirements of title V of the Federal Clean Air Act, and include all information necessary to determine qualification for, and to assure compliance with, the general permit. Without repeating the public participation procedures required under subdivision h of subsection 6, the department may grant a source's request for authorization to operate under a general permit, but such a grant shall not be a final permit action for purposes of judicial review.

e. Temporary sources. The department may issue a single permit authorizing emissions from similar operations by the same source owner or operator at multiple temporary locations. The operation must be temporary and involve at least one change of location during the term of the permit. No affected source shall be permitted as a temporary source. Permits for temporary sources shall include the following:

(1) Conditions that will assure compliance with all applicable requirements at all authorized locations;

(2) Requirements that the owner or operator notify the department at least ten days in advance of each change in location; and

(3) Conditions that assure compliance with all other provisions of this section.

f. Permit shield.

(1) Except as provided in this section, upon written request by the applicant, the department shall include in a title V permit to operate a provision stating that compliance with the conditions of the permit shall be deemed compliance with any applicable requirement as of the date of permit issuance, provided that:

(a) Such applicable requirements are included and are specifically identified in the permit; or

(b) The department, in acting on the permit application or revision, determines in writing that other requirements specifically identified are not applicable to the source, and the permit includes the determination or a concise summary thereof.

(2) A title V permit that does not expressly state that a permit shield exists shall be presumed not to provide such a shield.

(3) Nothing in this subdivision or in any title V permit shall alter or affect the following:

(a) The provisions of section 303 of the Federal Clean Air Act (emergency orders), including the authority of the administrator of the United States environmental protection agency under that section;

(b) The liability of an owner or operator of a source for any violation of applicable requirements prior to or at the time of permit issuance;

(c) The applicable requirements of the acid rain program, consistent with section 408(a) of the Federal Clean Air Act; or

(d) The ability of the United States environmental protection agency to obtain information from a source pursuant to section 114 of the Federal Clean Air Act.

g. Emergency provision.

(1) An "emergency" means any situation arising from sudden and reasonably unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emissions limitation under the title V permit to operate, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventive maintenance, careless or improper operation, or operator error.

(2) Effect of an emergency. An emergency constitutes an affirmative defense to an action brought for noncompliance with such technology-based emissions limitations if the conditions of paragraph 3 are met.

(3) The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:

(a) An emergency occurred and that the permittee can identify the causes of the emergency;

(b) The permitted facility was at the time being properly operated;

(c) During the period of the emergency the permittee took all reasonable steps to minimize levels of emissions that exceeded the emissions standards, or other requirements in the permit; and

(d) The permittee submitted notice of the emergency to the department within one working day of the time when emissions limitations were exceeded due to the emergency. This notice fulfills the requirement of item 2 of subparagraph c of paragraph 3 of subdivision a. This notice must contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

(4) In any enforcement proceeding, the permittee seeking to establish the occurrence of an emergency has the burden of proof.

(5) This provision is in addition to any emergency or upset provision contained in any applicable requirement and the malfunction notification required under subdivision b of subsection 2 of section 33-15-01-13 when a threat to health and welfare would exist.

6. **Permit issuance, renewal, reopenings, and revisions.**

a. Action on application.

(1) A permit, permit modification, or permit renewal may be issued only if all of the following conditions have been met:

(a) The department has received a complete application for a permit, permit modification, or permit renewal, except that a complete application need not be received before issuance of a general permit under subdivision d of subsection 5;

(b) Except for modifications qualifying for minor permit modification procedures under paragraphs 1 and 2

of subdivision e, the department has complied with the requirements for public participation under subdivision h;

(c) The department has complied with the requirements for notifying and responding to affected states under subdivision b of subsection 7;

(d) The conditions of the permit provide for compliance with all applicable requirements and the requirements of this section; and

(e) The administrator of the United States environmental protection agency has received a copy of the proposed permit and any notices required under subdivisions a and b of subsection 7, and has not objected to issuance of the permit under subdivision c of subsection 7 within the time period specified therein.

(2) Except for applications received during the initial transitional period described in 40 CFR 70.4(b)(11) or under regulations promulgated under title IV or title V of the Federal Clean Air Act for the permitting of affected sources under the acid rain program, the department shall take final action on each permit application, including a request for permit modification or renewal, within eighteen months after receiving a complete application.

(3) The department shall provide notice to the applicant of whether the application is complete. Unless the department requests additional information or otherwise notifies the applicant of incompleteness within sixty days of receipt of an application, the application shall be deemed complete. For modifications processed through the minor permit modification procedures, in paragraphs 1 and 2 of subdivision e, a completeness determination is not required.

(4) The department shall provide a statement that sets forth the legal and factual basis for the draft permit conditions, including references to the applicable statutory or regulatory provisions. The department shall send this statement to the United States environmental protection agency and to any other person who requests it.

(5) The submittal of a complete application shall not affect the requirement that any source have a permit to construct under section 33-15-14-02.

b. Requirement for a permit.

(1) Except as provided in the following sentence, paragraphs 2 and 3, subparagraph e of paragraph 1 of subdivision e, and subparagraph e of paragraph 2 of subdivision e, no title V source may operate after the time that it is required to submit a timely and complete application under this section, except in compliance with a permit issued under this section. If a title V source submits a timely and complete application for permit issuance, including for renewal, the source's failure to have a title V permit is not a violation of this section until the department takes final action on the permit application, except as noted in this subsection. This protection shall cease to apply if, subsequent to the completeness determination made pursuant to paragraph 3 of subdivision a, and as required by paragraph 2 of subdivision a of subsection 4, the applicant fails to submit by the deadline specified in writing by the department any additional information identified as being needed to process the application. For timely and complete renewal applications for which the department has failed to issue or deny the renewal permit before the expiration date of the previous permit, all the terms and conditions of the permit, including the permit shield that was granted pursuant to subdivision f of subsection 5 shall remain in effect until the renewal permit has been issued or denied.

(2) A permit revision is not required for section 502(b)(10) changes provided:

(a) The changes are not modifications under chapters 33-15-12, 33-15-13, and 33-15-15 or title I of the Federal Clean Air Act.

(b) The changes do not exceed the emissions allowable under the title V permit whether expressed therein as a rate of emissions or in terms of total emissions.

(c) A permit to construct under section 33-15-14-02 has been issued, if required.

(d) The facility provides the department and the administrator of the United States environmental protection agency with written notification at least seven days in advance of the proposed change. The written notification shall include a description of each change within the permitted facility, the date on which the change will occur, any change in emissions, and any permit term or condition that is no longer applicable as a result of the change.

The permit shield described in subdivision f of subsection 5 shall not apply to any change made pursuant to this paragraph.

(3) A permit revision is not required for changes that are not addressed or prohibited by the permit provided:

(a) Each such change shall meet all applicable requirements and shall not violate any existing permit term or condition.

(b) The source must provide contemporaneous written notice to the department and the administrator of the United States environmental protection agency of each such change, except for changes that qualify as insignificant under the provisions of subdivision c of subsection 4. Such written notice shall describe each such change, including the date, any change in emissions, contaminants emitted, and any applicable requirement that would apply as a result of the change.

(c) The permittee shall keep a record describing changes made at the source that result in emissions of a regulated air contaminant subject to an applicable requirement, but not otherwise regulated under the permit, and the emissions resulting from those changes.

(d) The changes are not subject to any requirements under title IV of the Federal Clean Air Act.

(e) The changes are not modifications under chapters 33-15-12, 33-15-13, and 33-15-15 or any provision of title I of the Federal Clean Air Act.

(f) A permit to construct under section 33-15-14-02 has been issued, if required.

The permit shield described in subdivision f of subsection 5 shall not apply to any change made pursuant to this paragraph.

c. Permit renewal and expiration.

(1) Permits being renewed are subject to the same procedural requirements, including those for public participation, affected state and the United States environmental protection agency review, that apply to initial permit issuance; and

(2) Permit expiration terminates the source's right to operate unless a timely and complete renewal application has been submitted consistent with subdivision b of subsection 6 and subparagraph c of paragraph 1 of subdivision a of subsection 4.

d. Administrative permit amendments.

(1) An "administrative permit amendment" is a permit revision that:

(a) Corrects typographical errors;

(b) Identifies a change in the name, address, or ~~phone~~ telephone number of any person identified in the permit, or provides a similar minor administrative change at the source;

(c) Requires more frequent monitoring or reporting by the permittee;

(d) Allows for a change in ownership or operational control of a source ~~where~~ if the department determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee has been submitted to the department;

(e) Incorporates into the title V permit the requirements from a permit to construct, provided that the permit to construct review procedure is substantially equivalent to the requirements of subsections 6 and 7 that would be applicable to the change if it were subject to review as a permit modification, and compliance requirements substantially equivalent to those contained in subsection 5; or

(f) Incorporates any other type of change which the administrator of the United States environmental protection agency has approved as being an administrative permit amendment as part of the approved title V operating permit program.

(2) Administrative permit amendments for purposes of the acid rain portion of the permit shall be governed by regulations promulgated under title IV of the Federal Clean Air Act.

(3) Administrative permit amendment procedures. An administrative permit amendment may be made by the department consistent with the following:

(a) The department shall take no more than sixty days from receipt of a request for an administrative permit amendment to take final action on such request, and may incorporate such changes without providing notice to the public or affected states provided that it designates any such permit revisions as having been made pursuant to this subdivision.

(b) The department shall submit a copy of the revised permit to the administrator of the United States environmental protection agency.

(c) The source may implement the changes addressed in the request for an administrative amendment immediately upon submittal of the request provided a permit to construct under section 33-15-14-02 has been issued, if required.

(4) The department may, upon taking final action granting a request for an administrative permit amendment, allow coverage by the permit shield in subdivision f of subsection 5 for administrative permit amendments made pursuant to subparagraph e of paragraph 1 of subdivision d which meet the relevant requirements of subsections 5, 6, and 7 for significant permit modifications.

e. Permit modification. A permit modification is any revision to a title V permit that cannot be accomplished under the provisions for administrative permit amendments under subdivision d. A permit modification for purposes of the acid rain portion of the permit shall be governed by regulations promulgated under title IV of the Federal Clean Air Act.

(1) Minor permit modification procedures.

(a) Criteria.

[1] Minor permit modification procedures may be used only for those permit modifications that:

[a] Do not violate any applicable requirement;

[b] Do not involve significant changes to existing monitoring, reporting, or recordkeeping requirements in the permit;

[c] Do not require or change a case-by-case determination of an emissions limitation or other standard, or a source-specific determination for temporary sources of ambient impacts, or a visibility or increment analysis;

[d] Do not seek to establish or change a permit term or condition for which there is no corresponding underlying applicable requirement and that the source has assumed to avoid an applicable requirement to which the source would otherwise be subject. Such terms and conditions include a federally enforceable emissions cap assumed to avoid classification as a modification under any provision of title I of the Federal Clean Air Act; and an alternative emissions limit approved pursuant to regulations promulgated under section 112(i)(5) of the Federal Clean Air Act;

[e] Are not modifications under chapters 33-15-12, 33-15-13, and 33-15-15 or any provision of title I of the Federal Clean Air Act; and

[f] Are not required to be processed as a significant modification.

[2] Notwithstanding item 1 and subparagraph a of paragraph 2 of subdivision e, minor permit modification procedures may be used for permit modifications involving the use of economic incentives, marketable permits, emissions trading, and other similar approaches, to the extent that such minor permit modification procedures are explicitly provided for in the state implementation plan, or in applicable requirements promulgated by the United States environmental protection agency.

(b) Application. An application requesting the use of minor permit modification procedures shall meet the requirements of subdivision c of subsection 4 and shall include the following:

[1] A description of the change, the emissions resulting from the change, and any new applicable requirements that will apply if the change occurs;

[2] The source's suggested draft permit;

[3] Certification by a responsible official, consistent with subdivision d of subsection 4, that the proposed modification meets the criteria for use of minor permit modification procedures and a request that such procedures be used; and

[4] Completed forms for the department to use to notify the administrator of the United States environmental protection agency and affected states as required under subsection 7.

(c) United States environmental protection agency and affected state notification. Within five working days of receipt of a complete permit modification application, the department shall notify the administrator of the United States environmental protection agency and affected states of the requested permit modification. The department shall promptly send any notice required under paragraph 2 of subdivision b of subsection 7 to the administrator of the United States environmental protection agency.

(d) Timetable for issuance. The department may not issue a final permit modification until after the United States environmental protection agency forty-five-day review period or until the United States environmental protection agency has notified the department that the United States environmental protection agency will not object to issuance of the permit modification, whichever is first, although the department can approve the permit modification prior to that time. Within ninety days of the department's receipt of an application under minor permit modification procedures or fifteen days after the end of the administrator's forty-five-day review period under subdivision c of subsection 7, whichever is later, the department shall:

[1] Issue the permit modification as proposed;

[2] Deny the permit modification application;

[3] Determine that the requested modification does not meet the minor permit modification criteria and should be reviewed under the significant modification procedures; or

[4] Revise the draft permit modification and transmit to the administrator the new proposed permit modification as required by subdivision a of subsection 7.

(e) Source's ability to make change. A source may make the change proposed in its minor permit modification application only after it files such application and the department approves the change in writing. If the department allows the source to make the proposed change prior to taking action specified in items 1, 2, and 3 of subparagraph d, the source must comply with both the applicable requirements governing the change and the proposed permit terms and conditions. During this time period, the source need not comply with the existing permit terms and conditions it seeks to modify. However, if the source fails to comply with its proposed permit terms and conditions during this time period, the existing permit terms and conditions it seeks to modify may be enforced against it.

(f) The permit shield under subdivision f of subsection 5 shall not extend to minor permit modifications.

(2) Group processing of minor permit modifications. Consistent with this paragraph, the department may modify the procedure outlined in paragraph 1 to process groups of a source's applications for certain modifications eligible for minor permit modification processing.

(a) Criteria. Group processing of modifications may be used only for those permit modifications:

[1] That meet the criteria for minor permit modification procedures under item 1 of subparagraph a of paragraph 1 of subdivision e; and

[2] That collectively are below the threshold level which is ten percent of the emissions allowed by the permit for the emissions unit for which the change is requested, twenty percent of the applicable definition of major source in

subsection 1, or five tons [4.54 metric tons] per year, whichever is least.

(b) Application. An application requesting the use of group processing procedures shall meet the requirements of subdivision c of subsection 4 and shall include the following:

[1] A description of the change, the emissions resulting from the change, and any new applicable requirements that will apply if the change occurs.

[2] The source's suggested draft permit.

[3] Certification by a responsible official, consistent with subdivision d of subsection 4, that the proposed modification meets the criteria for use of group processing procedures and a request that such procedures be used.

[4] A list of the source's other pending applications awaiting group processing, and a determination of whether the requested modification, aggregated with these other applications, equals or exceeds the threshold set under item 2 of subparagraph a of paragraph 2 of subdivision e.

[5] Certification, consistent with subdivision d of subsection 4, that the source has notified the United States environmental protection agency of the proposed modification. Such notification need only contain a brief description of the requested modification.

[6] Completed forms for the department to use to notify the administrator of the United States environmental protection agency and affected states as required under subsection 7.

(c) United States environmental protection agency and affected state notification. On a quarterly basis or within five business days of receipt of an application demonstrating that the aggregate of a source's pending applications equals or exceeds the threshold level set under item 2 of subparagraph a of paragraph 2 of subdivision e, whichever is earlier, the department shall meet its obligation under paragraph 1 of subdivision a of subsection 7 and paragraph 1 of subdivision b of

subsection 7 to notify the administrator of the United States environmental protection agency and affected states of the requested permit modifications. The department shall send any notice required under paragraph 2 of subdivision b of subsection 7 to the administrator of the United States environmental protection agency.

(d) Timetable for issuance. The provisions of subparagraph d of paragraph 1 of subdivision e shall apply to modifications eligible for group processing, except that the department shall take one of the actions specified in items 1 through 4 of subparagraph d of paragraph 1 of subdivision e within one hundred eighty days of receipt of the application or fifteen days after the end of the administrator's forty-five-day review period under subdivision c of subsection 7, whichever is later.

(e) Source's ability to make change. The provisions of subparagraph e of paragraph 1 apply to modifications eligible for group processing.

(f) The permit shield under subdivision f of subsection 5 shall not extend to group processing of minor permit modifications.

(3) Significant modification procedures.

(a) Criteria. Significant modification procedures shall be used for applications requesting permit modifications that do not qualify as minor permit modifications or as administrative amendments. Every significant change in existing monitoring permit terms or conditions and every relaxation of reporting or recordkeeping permit terms or conditions shall be considered significant. Nothing herein shall be construed to preclude the permittee from making changes consistent with this subsection that would render existing permit compliance terms and conditions irrelevant.

(b) Significant permit modifications shall meet all requirements of this section, including those for applications, public participation, review by affected states, and review by the United States environmental protection agency, as they apply to permit issuance and permit renewal. The department shall complete review of significant permit modifications within nine months after receipt of a complete application.

f. Reopening for cause.

(1) Each issued permit shall include provisions specifying the conditions under which the permit will be reopened prior to the expiration of the permit. A permit shall be reopened and revised under any of the following circumstances:

(a) Additional applicable requirements under the Federal Clean Air Act become applicable to a major title V source with a remaining permit term of three or more years. Such a reopening shall be completed not later than eighteen months after promulgation of the applicable requirement. No such reopening is required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions has been extended.

(b) Additional requirements, including excess emissions requirements, become applicable to an affected source under title IV of the Federal Clean Air Act or the regulations promulgated thereunder. Upon approval by the administrator of the United States environmental protection agency, excess emissions offset plans shall be deemed to be incorporated into the permit.

(c) The department or the United States environmental protection agency determines that the permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the permit.

(d) The administrator of the United States environmental protection agency or the department determines that the permit must be revised or revoked to assure compliance with the applicable requirements.

(2) Proceedings to reopen and issue a permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of the permit for which cause to reopen exists. Such reopening shall be made as expeditiously as practicable.

(3) Reopenings under paragraph 1 shall not be initiated before a notice of such intent is provided to the title V source by the department at least thirty days in advance of the date that the permit is to be reopened, except that the department may provide a shorter time period in the case of an emergency.

g. Reopenings for cause by the United States environmental protection agency.

(1) If the administrator of the United States environmental protection agency finds that cause exists to terminate, modify, or revoke and reissue a permit pursuant to subdivision f, within ninety days after receipt of such notification, the department shall forward to the United States environmental protection agency a proposed determination of termination, modification, or revocation and reissuance, as appropriate.

(2) The administrator of the United States environmental protection agency will review the proposed determination from the department within ninety days of receipt.

(3) The department shall have ninety days from receipt of the United States environmental protection agency objection to resolve any objection that the United States environmental protection agency makes and to terminate, modify, or revoke and reissue the permit in accordance with the administrator's objection.

(4) If the department fails to submit a proposed determination or fails to resolve any objection, the administrator of the United States environmental protection agency will terminate, modify, or revoke and reissue the permit after taking the following actions:

(a) Providing at least thirty days' notice to the permittee in writing of the reasons for any such action.

(b) Providing the permittee an opportunity for comment on the administrator's proposed action and an opportunity for a hearing.

h. Public participation. Except for modifications qualifying for minor permit modification procedures, all permit proceedings, including initial permit issuance, significant modifications, and renewals, shall be subject to procedures for public notice including offering an opportunity for public comment and a hearing on the draft permit. These procedures shall include the following:

(1) Notice shall be given by publication in a newspaper of general circulation in the area where the source is located or in a state publication designed to give general public notice; to persons on a mailing list developed by the department, including those who request in writing to be on the list; and by other means if necessary to assure adequate notice to the affected public;

(2) The notice shall identify the affected facility; the name and address of the permittee; the name and address of the department; the activity or activities involved in the permit action; the emissions change involved in any permit modification; the name, address, and telephone number of a person from whom interested persons may obtain additional information, including copies of the permit draft, the application, all relevant supporting materials, and all other materials available to the department that are relevant to the permit decision; a brief description of the comment procedures required by this subsection; and the time and place of any hearing that may be held, including a statement of procedures to request a hearing, unless a hearing has already been scheduled;

(3) The department shall provide such notice and opportunity for participation by affected states as is provided for by subsection 7;

(4) The department shall provide at least thirty days for public comment and shall give notice of any public hearing at least thirty days in advance of the hearing; and

(5) The department shall keep a record of the commenters and also of the issues raised during the public participation process. These records shall be available to the public.

7. **Permit review by the United States environmental protection agency and affected states.**

a. Transmission of information to the administrator.

(1) The department shall provide a copy of each permit application including any application for a permit modification (including the compliance plan), to the administrator of the United States environmental protection agency except that the applicant shall provide such information directly to the administrator of the United States environmental protection agency when directed to do so by the department. The department shall provide a copy of each proposed permit and each final title V permit to operate to the administrator of the United States environmental protection agency. To the extent practicable, the preceding information shall be provided in computer-readable format compatible with the United States environmental protection agency's national data base management system.

(2) The department may waive the requirements of paragraph 1 and paragraph 1 of subdivision b for any category of sources

(including any class, type, or size within such category) other than major sources upon approval by the administrator of the United States environmental protection agency.

(3) The department shall keep these records for at least five years.

b. Review by affected states.

(1) The department shall give notice of each draft permit to any affected state on or before the time that the notice to the public under subdivision h of subsection 6 is given, except to the extent paragraphs 1 and 2 of subdivision e of subsection 6 require the timing of the notice to be different.

(2) As part of the submittal of the proposed permit to the administrator of the United States environmental protection agency (or as soon as possible after the submittal for minor permit modification procedures allowed under paragraphs 1 and 2 of subdivision e of subsection 6) the department shall notify the administrator of the United States environmental protection agency and any affected state in writing of any refusal by the department to accept all recommendations for the proposed permit that the affected state submitted during the public or affected state review period. The notice shall include the department's reasons for not accepting any such recommendation. The department is not required to accept recommendations that are not based on applicable requirements or the requirements of this section.

c. United States environmental protection agency objection. No permit for which an application must be transmitted to the administrator of the United States environmental protection agency under subdivision a shall be issued if the administrator of the United States environmental protection agency objects to its issuance in writing within forty-five days of receipt of the proposed permit and all necessary supporting information.

d. Public petitions to the administrator of the United States environmental protection agency. If the administrator of the United States environmental protection agency does not object in writing under subdivision c, any person may petition the administrator of the United States environmental protection agency within sixty days after the expiration of the administrator's forty-five-day review period to make such objection. Any such petition shall be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided for in subdivision h of subsection 6, unless the petitioner demonstrates that it was impracticable to raise such objections within such

period, or unless the grounds for such objection arose after such period. If the administrator of the United States environmental protection agency objects to the permit as a result of a petition filed under this subdivision, the department shall not issue the permit until the United States environmental protection agency's objection has been resolved, except that a petition for review does not stay the effectiveness of a permit or its requirements if the permit was issued after the end of the forty-five-day review period and prior to the United States environmental protection agency's objection. If the department has issued a permit prior to receipt of the United States environmental protection agency's objection under this subdivision, the department may thereafter issue only a revised permit that satisfies the United States environmental protection agency's objection. In any case, the source will not be in violation of the requirement to have submitted a timely and complete application.

e. Prohibition on default issuance. The department shall issue no title V permit to operate, including a permit renewal or modification, until affected states and the United States environmental protection agency have had an opportunity to review the proposed permit as required under this subsection.

8. **Judicial review of title V permit to operate decisions.**

a. The applicant, any person who participated in the department's public participation process, and any other person who could obtain judicial review under North Dakota Century Code section 28-32-15 may obtain judicial review provided such appeal is filed in accordance with North Dakota Century Code section 28-32-15 within thirty days after notice of the final permit action.

b. The department's failure to take final action on an application for a permit, permit renewal, or permit revision within the timeframes referenced in this section shall be appealable in accordance with North Dakota Century Code section 28-32-15 within thirty days after expiration of the applicable timeframes.

c. In accordance with North Dakota Century Code chapter 28-32, the mechanisms outlined in this subsection shall be the exclusive means for judicial review of permit decisions referenced in this section.

d. Solely for the purpose of obtaining judicial review in state court, final permit action shall include the failure of the department to take final action on an application for a permit, permit renewal, or permit revision within the timeframes referenced in this section.

e. Failure to take final action within ninety days of receipt of an application requesting minor permit modification procedures (or one hundred eighty days for modifications subject to group processing requirements) shall be considered final action and subject to judicial review in state court.

9. **Enforcement.** The department may suspend, revoke, or terminate a permit for violations of this article, violation of any permit condition or for failure to respond to a notice of violation or any order issued pursuant to this article. A permit to operate which has been revoked or terminated pursuant to this article must be surrendered forthwith to the department. No person may operate or cause the operation of a source if the department denies, terminates, revokes, or suspends a permit to operate.

10. **Compliance assurance monitoring.** Except as noted below, title 40, Code of Federal Regulations, part 64 compliance assurance monitoring, ~~as published in the federal register on October 22, 1997,~~ as it exists on January 31, 2002, is incorporated by reference.

    a. "Administrator" means the department except for those duties that cannot be delegated by the United States environmental protection agency. For those duties that cannot be delegated, administrator means the department and the administrator of the United States environmental protection agency.

    b. "Part 70 permit" means a title V permit to operate.

    c. "Permitting authority" means the department.

History: Effective March 1, 1994; amended effective December 1, 1994; August 1, 1995; January 1, 1996; September 1, 1997; September 1, 1998; March 1, 2003.
General Authority: NDCC 23-25-03, 23-25-04, 23-25-04.1
Law Implemented: NDCC 23-25-03, 23-25-04, 23-25-04.1, 23-25-10

CHAPTER 33-15-15

33-15-15-01. General provisions.

1. **Definitions.** For the purposes of this chapter:

   a. "Actual emissions" means the actual rate of emissions of a contaminant from an emissions unit, as determined in accordance with paragraphs 1 through 4.

      (1) In general, actual emissions as of a particular date must equal the average rate, in tons per year, at which the unit actually emitted the contaminant during a two-year period which precedes the particular date and which is representative of normal source operation. The department may allow the use of a different time period upon a determination that it is more representative of normal source operation. Actual emissions must be calculated using the unit's actual operating hours, production rates, and types of materials processed, stored, or combusted during the selected time period.

      (2) The department may presume that source-specific allowable emissions for the unit are equivalent to the actual emissions of the unit.

      (3) For any emissions unit (other than an electric utility steam generating unit specified in paragraph 4) which has not begun normal operations on the particular date, actual emissions shall equal the potential to emit of the unit on that date.

      (4) For an electric utility steam generating unit (other than a new unit or the replacement of an existing unit) actual emissions of the unit following the physical or operational change shall equal the representative actual annual emissions of the unit following the physical or operational change, provided the source owner or operator maintains and submits to the reviewing authority, on an annual basis for a period of five years from the date the unit resumes regular operation, information demonstrating that the physical or operational change did not result in an emissions increase. A longer period, not to exceed ten years, may be required by the department if it determines such a period to be more representative of normal source postchange operations.

   b. "Allowable emissions" means the emission rate of a stationary source calculated using the maximum rated capacity of the source (unless the source is subject to enforceable construction permit conditions which restrict the operating rate, or hours of operation, or both) and the most stringent of the following:

(1) Applicable standards of performance or emission limitations as set forth in this article.

(2) The emission rate specified as an enforceable permit condition.

c. "Baseline area" means any intrastate area (and every part thereof) designated as attainment or unclassifiable under section 107(d)(1)(D) or (E) of the Federal Clean Air Act [Pub. L. 95-95] in which the major source or major modification establishing the minor source baseline date would construct or would have an air quality impact equal to or greater than one ug/m^3 (annual average) of the contaminant for which the minor source baseline date is established. Any baseline area established originally for the total suspended particulate increments shall remain in effect and shall apply for purposes of determining the amount of available PM_{10} increments, except that such baseline area shall not remain in effect if the department rescinds the corresponding minor source baseline date in accordance with paragraph 4 of subdivision e. North Dakota is divided into two intrastate areas under section 107(d)(1)(D) or (E) of the Federal Clean Air Act [Pub. L. 95-95]: the Cass County portion of Region No. 130, the Metropolitan Fargo-Moorhead Interstate Air Quality Control Region; and Region No. 172, the North Dakota Intrastate Air Quality Control Region (the remaining fifty-two counties).

d. (1) "Baseline concentration" means that ambient concentration level which exists in the baseline area at the time of the applicable minor source baseline date. A baseline concentration is determined for each contaminant for which a minor source baseline date is established and includes:

(a) The actual emissions representative of sources in existence on the applicable minor source baseline date, except as provided in paragraph 2;

(b) The allowable emissions of major stationary sources which commenced construction before the major source baseline date but were not in operation by the applicable minor source baseline date.

(2) The following will not be included in the baseline concentration and will affect the applicable maximum allowable increases:

(a) Actual emissions from any major stationary source on which construction commenced after the major source baseline date; and

(b) Actual emissions increases and decreases at any stationary source occurring after the minor source baseline date.

e. (1) "Major source baseline date" means:

(a) In the case of particulate matter and sulfur dioxide, January 6, 1975; and

(b) In the case of nitrogen dioxide, February 8, 1988.

(2) "Minor source baseline date" means the earliest date after the trigger date on which a major stationary source or a major modification subject to requirements of this chapter submits a complete application under the relevant regulations. The trigger date is:

(a) In the case of particulate matter and sulfur dioxide, August 7, 1977; and

(b) In the case of nitrogen dioxide, February 8, 1988.

(3) The baseline date is established for each contaminant for which increments or other equivalent measures have been established if:

(a) The area in which the proposed source or modification would construct is designated as attainment or unclassifiable under section 107(d)(1)(D) or (E) of the Federal Clean Air Act [Pub. L. 95-95] for the contaminant on the date of its complete application under this chapter; and

(b) In the case of a major stationary source, the contaminant would be emitted in significant amounts or, in the case of a major modification, there would be a significant net emissions increase of the contaminant.

(4) Any minor source baseline date established originally for the total suspended particulate increments shall remain in effect and shall apply for purposes of determining the amount of available PM_{10} increments, except that the department may rescind any such minor source baseline date where it can be shown by the applicant, to the satisfaction of the department, that the emissions increase from the major stationary source, or the net emissions increase from the major modification, responsible for triggering that date did not result in a significant amount of PM_{10} emissions.

(5) The department shall provide a list of baseline dates for each contaminant for each baseline area.

f. "Begin actual construction" means, in general, initiation of physical onsite construction activities on an emissions unit which are of a permanent nature. Such activities include installation of building supports and foundations, laying of underground pipework, and construction of permanent storage structures. With respect to a change in method of operation, this term refers to those onsite activities, other than preparatory activities, which mark the initiation of the change.

g. "Best available control technology" means an emission limitation (including a visible emission standard) based on the maximum degree of reduction for each contaminant subject to regulation under North Dakota Century Code chapter 23-25 which would be emitted from any proposed major stationary source or major modification which the department, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such source or modification through application of production processes or available methods, systems, and techniques including fuel cleaning or treatment or innovative fuel combustion techniques for control of such contaminant. In no event may application of "best available control technology" result in emissions of any contaminant which would exceed the emissions allowed by any applicable standards of performance under chapters 33-15-12 and 33-15-13. If the department determines that technological or economic limitations on the application of measurement methodology to a particular emissions unit would make the imposition of an emission standard infeasible, a design, equipment, work practice or operational standard, or combination thereof, may be prescribed instead to satisfy the requirement for the application of best available control technology. Such standard must, to the degree possible, set forth the emissions reduction achievable by implementation of such design, equipment, work practice, or operation, and shall provide for compliance by means which achieve equivalent results.

h. "Clean coal technology" means any technology, including technologies applied at the precombustion, combustion, or postcombustion stage, at a new or existing facility which will achieve significant reductions in air emissions of sulfur dioxide or oxides of nitrogen associated with the utilization of coal in the generation of electricity, or process steam which was not in widespread use as of November 15, 1990.

i. "Clean coal technology demonstration project" means a project using funds appropriated under the heading "department of energy-clean coal technology", up to a total amount of two billion

five hundred million dollars for commercial demonstration of clean coal technology, or similar projects funded through appropriations for the United States environmental protection agency. The federal contribution for a qualifying project shall be at least twenty percent of the total cost of the demonstration project.

j. "Commence" as applied to construction of a major stationary source or major modification means that the owner or operator has obtained all necessary preconstruction permits and either has (1) begun, or caused to begin, a continuous program of actual onsite construction of the source, to be completed within a reasonable time; or (2) entered into binding agreements or contractual obligations, which cannot be canceled or modified without substantial loss to the owner or operator, to undertake a program of construction of the source to be completed within a reasonable time.

k. "Complete" means, in reference to an application for a permit, that the application contains all of the information necessary for processing the application. Designating an application complete for purposes of permit processing does not preclude the reviewing authority from requesting or accepting any additional information.

l. "Construction" means any physical change or change in the method of operation (including fabrication, erection, installation, demolition, or modification of an emissions unit) which would result in a change in actual emissions.

m. "Electric utility steam generating unit" means any steam electric generating unit that is constructed for the purpose of supplying more than one-third of its potential electric output capacity and more than twenty-five megawatts electrical output to any utility power distribution system for sale. Any steam supplied to a steam distribution system for the purpose of providing steam to a steam-electric generator that would produce electrical energy for sale is also considered in determining the electrical energy output capacity of the affected facility.

n. "Emissions unit" means any part of a stationary source which emits or would have the potential to emit any air contaminant regulated under North Dakota Century Code chapter 23-25; or

o. "Enforceable" means all limitations and conditions which are enforceable by the department pursuant to this article and any applicable requirements within the North Dakota state implementation plan.

p. "Facility, building, structure, or installation" means all of the air contaminant emitting activities which belong to the same

industrial grouping, are located on one or more contiguous or adjacent properties, and are under the control of the same person (or persons under common control). Air contaminant emitting activities shall be considered as part of the same industrial grouping if they belong to the same "major group" (i.e., which have the same two-digit code) as described in the Standard Industrial Classification Manual, 1972, as amended by the 1977 Supplement (United States government printing office stock numbers 4101-0066 and 003-005-00176-0, respectively).

q. "Federal land manager" means, with respect to any lands in the United States, the secretary of the department with authority over such lands.

r. "Fugitive emissions" means those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening.

s. "High terrain" means any area having an elevation nine hundred feet [271.32 meters] or more above the base of the stack of a source.

t. "Indian governing body" means the governing body of any tribe, band, or group of Indians subject to the jurisdiction of the United States and recognized by the United States as possessing power of self-government.

u. "Indian reservation" means any federally recognized reservation established by treaty, agreement, executive order, or Act of Congress.

v. "Innovative control technology" means any system of air pollution control that has not been adequately demonstrated in practice, but would have a substantial likelihood of achieving greater continuous emissions reduction than any control system in current practice or of achieving at least comparable reductions at lower cost in terms of energy, economics, or nonair quality environmental impacts.

w. "Low terrain" means any area other than high terrain.

x. "Major modification" means any physical change in, or change in the method of operation of a major stationary source that would result in a significant net emissions increase of any air contaminant subject to regulation under North Dakota Century Code chapter 23-25.

(1) Any net emissions increase that is significant for volatile organic compounds must be considered significant for ozone.

(2) A physical change or change in the method of operation does not include:

(a) Routine maintenance, repair, and replacement.

(b) Use of an alternate fuel or raw material by reason of any order under sections 2(a) and (b) of the Energy Supply and Environmental Coordination Act of 1974 (or any superseding legislation) or by reason of a natural gas curtailment plan pursuant to the Federal Power Act.

(c) Use of an alternate fuel or raw material by a stationary source which:

[1] The source was capable of accommodating before January 6, 1975, unless such change would be prohibited under any state enforceable permit condition which was established after January 6, 1975, pursuant to this chapter or under regulations approved pursuant to North Dakota Century Code chapter 23-25; or

[2] The source is approved to use under any permit issued under regulations approved pursuant to North Dakota Century Code chapter 23-25.

(d) An increase in the hours of operation or in the production rate, unless such change would be prohibited under any federally enforceable permit condition which was established after January 6, 1975, pursuant to and in accordance with this chapter ~~under regulations approved pursuant to North Dakota Century Code chapter 23-25~~, section 33-15-14-02, or section 33-15-14-03.

(e) Any change in ownership of a stationary source.

(f) Use of an alternative fuel by reason of an order or rule under section 125 of the Federal Clean Air Act [Pub. L. 95-95].

(g) Use of an alternative fuel at a steam generating unit to the extent that the fuel is generated from municipal solid waste.

(h) The addition, replacement, or use of a pollution control project at an existing electric utility steam generating unit, unless the administrator of the United States environmental protection agency determines that such addition, replacement, or use renders the unit less environmentally beneficial, or except:

[1] When the administrator of the United States environmental protection agency has reason to believe that the pollution control project would result in a significant net increase in representative actual annual emissions of any criteria pollutant over levels used for that source in the most recent air quality impact analysis in the area conducted, if any; and

[2] The administrator of the United States environmental protection agency determines that the increase will cause or contribute to a violation of any national ambient air quality standard or PSD increment, or visibility limitation.

(i) The installation, operation, cessation, or removal of a temporary clean coal technology demonstration project, provided that the project complies with:

[1] The North Dakota state implementation plan; and

[2] Other requirements necessary to attain and maintain the national ambient air quality standards during the project and after it is terminated.

(j) The installation or operation of a permanent clean coal technology demonstration project that constitutes repowering, provided that the project does not result in an increase in the potential to emit of any regulated pollutant emitted by the unit. This exemption shall apply on a pollutant-by-pollutant basis.

(k) The reactivation of a very clean coal-fired electric utility steam generating unit.

y. "Major stationary source" means:

(1) Any of the following stationary sources of air contaminants which emit, or have the potential to emit, one hundred tons [90718.17 kilograms] per year or more of any air contaminant regulated under North Dakota Century Code chapter 23-25:

coal cleaning plants (with thermal dryers), kraft pulp mills, portland cement plants, primary zinc smelters, iron and steel mills, primary aluminum ore reduction plants, primary copper smelters, municipal incinerators capable of charging more than two hundred fifty tons [226796.19 kilograms] of refuse per day, hydrofluoric, sulfuric, and nitric acid plants, petroleum refineries, lime plants, phosphate rock processing plants, coke oven batteries, sulfur recovery plants, carbon black plants (furnace process), primary lead smelters, fuel conversion plants, sintering plants, secondary metal production facilities, chemical process plants, fossil-fuel boilers and fossil fuel-fired steam electric plants (or combinations thereof) of more than two hundred fifty million British thermal units per hour heat input, petroleum storage and transfer units with a total storage capacity exceeding three hundred thousand barrels, taconite ore processing facilities, glass fiber processing plants, and charcoal production facilities.

(2) Notwithstanding the source sizes in paragraph 1, such term also includes any stationary source which emits, or has the potential to emit, two hundred fifty tons [226796.19 kilograms] per year or more of any air contaminant regulated under North Dakota Century Code chapter 23-25 or as outlined in paragraph 3.

(3) Any physical change that would occur at a stationary source not otherwise qualifying under paragraph 1 as a major stationary source, if the changes would constitute a major stationary source by itself.

(4) A major source that is major for volatile organic compounds shall be considered major for ozone.

(5) The fugitive emissions of a stationary source may not be included in determining for any of the purposes of this subdivision whether it is a major stationary source unless the source belongs to one of the categories of stationary sources in paragraph 1 and any other stationary source category which as of August 7, 1980, is being regulated under section 111 or 112 of the Federal Clean Air Act.

z. "Necessary preconstruction permits" means those permits required under this article.

aa. "Net emissions increase" means the amount by which the sum of the following exceeds zero:

(1) Any increase in actual emissions from a particular physical change or change in the method of operation at a stationary source; and

(2) Any other increases and decreases in actual emissions at the source that are contemporaneous with the particular change and are otherwise creditable.

(a) An increase or decrease in actual emissions is contemporaneous with the increase from the particular change only if it occurs between:

[1] The date five years before construction on the particular change commences; and

[2] The date that the increase from the particular change occurs.

(b) An increase or decrease in actual emissions is creditable only if the department has not relied on it in issuing a permit for the source under this article, which permit is in effect when the increase in actual emissions from the particular change occurs.

(c) An increase or decrease in actual emissions of sulfur dioxide, particulate matter, or nitrogen oxides which occurs before the applicable minor source baseline date is creditable only if it is required to be considered in calculating the amount of maximum allowable increases remaining available. With respect to particulate matter, only PM_{10} emissions can be used to evaluate the net emissions increase for PM_{10}.

(d) An increase in actual emissions is creditable only to the extent that the new level of actual emissions exceeds the old level.

(e) A decrease in actual emissions is creditable only to the extent that:

[1] The old level of actual emissions or the old level of allowable emissions, whichever is lower, exceeds the new level of actual emissions;

[2] It is enforceable at and after the time that actual construction on the particular change begins; and

[3] It has approximately the same qualitative significance for public health and welfare as

that attributed to the increase from the particular change.

(f) An increase that results from a physical change at a source occurs when the emissions unit on which construction occurred becomes operational and begins to emit a particular pollutant. Any replacement unit that requires shakedown becomes operational only after a reasonable shakedown period, not to exceed one hundred eighty days.

bb. "Pollution control project" means any activity or project undertaken at an existing electric utility steam generating unit for purposes of reducing emissions from each unit. Such activities or projects are limited to:

(1) The installation of conventional or innovative pollution control technology, including advanced flue gas desulfurization, sorbent injection for sulfur dioxide and nitrogen oxides controls, and electrostatic precipitators.

(2) An activity or project to accommodate switching to a fuel which is less polluting than the fuel used prior to the activity or project, including natural gas or coal reburning, or the cofiring of natural gas and other fuels for the purpose of controlling emissions.

(3) A permanent clean coal technology demonstration project conducted under title II, section 101(d) of the Further Continuing Appropriations Act of 1985 (section 5903(d) of title 42 of the United States Code), or subsequent appropriations, up to a total amount of two billion five hundred million dollars for commercial demonstration of clean coal technology, or similar projects funded through appropriations for the United States environmental protection agency.

(4) A permanent clean coal technology demonstration project that constitutes a repowering project.

cc. "Potential to emit" means the maximum capacity of a stationary source to emit an air contaminant under its physical and operational design. Any physical or operational limitation on the capacity of the source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, must be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable. Secondary emissions do not count in determining the potential to emit of a stationary source.

dd. "Reactivation of a very clean coal-fired electric utility steam generating unit" means any physical change or change in the method of operation associated with the commencement of commercial operations by a coal-fired utility unit after a period of discontinued operation when the unit:

(1) Has not been in operation for the two-year period prior to the enactment of the Clean Air Act Amendments of 1990, and the emissions from such unit continue to be carried in the department's emissions inventory at the time of enactment.

(2) Was equipped prior to shutdown with a continuous system or emissions control that achieves a removal efficiency of sulfur dioxide of no less than eighty-five percent and a removal efficiency of particulates of no less than ninety-eight percent.

(3) Is equipped with low-nitrogen oxide burners prior to the time of commencement of operations following reactivation.

(4) Is otherwise in compliance with the requirements of the Clean Air Act.

ee. "Representative actual annual emissions" means the average rate, in tons per year, at which the source is projected to emit a pollutant for the two-year period after a physical change or change in the method of operation of a unit (or a different consecutive two-year period within ten years after that change, where the department determines that such period is more representative of normal source operations), considering the effect any such change will have on increasing or decreasing the hourly emissions rate and on projected capacity utilization. In projecting future emissions the department shall:

(1) Consider all relevant information, including historical operational data, the company's own representations, filings with the state or federal regulatory authorities, and compliance plans under title IV of the Federal Clean Air Act.

(2) Exclude, in calculating any increase in emissions that results from the particular physical change or change in the method of operation at an electric utility steam generating unit, that portion of the unit's emissions following the change that could have been accommodated during the representative baseline period and is attributable to an increase in projected capacity utilization at the unit that is unrelated to the particular change, including any increased utilization due to the rate of electricity demand growth for the utility system as a whole.

ff. "Repowering" means replacement of an existing coal-fired boiler with one of the following clean coal technologies: atmospheric or pressurized fluidized bed combustion, integrated gasification combination cycle, magnetohydrodynamics, direct and indirect coal-fired turbines, integrated gasification fuel cells, or as determined by the administrator of the United States environmental protection agency, in consultation with the secretary of energy, a derivative of one or more of these technologies, and any other technology capable of controlling multiple combustion emissions simultaneously with improved boiler or generation efficiency and with significantly greater waste reduction relative to the performance of technology in widespread commercial use as of November 15, 1990.

(1) Repowering shall also include any unit fired by oil or gas, or both, which has been awarded clean coal technology demonstration funding as of January 1, 1991, by the department of energy.

(2) The administrator of the United States environmental protection agency shall give expedited consideration to permit applications for any source that satisfies the requirements of this subsection and is granted an extension under section 409 of the Federal Clean Air Act.

gg. "Secondary emissions" means emissions which occur as a result of the construction or operation of a major stationary source or major modification, but do not come from the major stationary source or major modification itself. Secondary emissions must be specific, well-defined, quantifiable, and impact the same general areas as the major stationary source or major modification which causes the secondary emissions. Secondary emissions include emissions from any offsite support facility which would not otherwise be constructed or increase its emissions except as a result of the construction or operation of the major stationary source or major modification. Secondary emissions do not include any emissions which come directly from a mobile source.

hh. "Significant" means:

(1) In reference to a net emissions increase or the potential of a source to emit any of the following air contaminants, a rate of emissions that would equal or exceed any of the following rates:

Air Contaminant and Emissions Rate

Carbon monoxide: 100 tons per year

Nitrogen oxides: 40 tons per year

Sulfur dioxide: 40 tons per year

Particulate matter: 25 tons per year of particulate matter emissions; 15 tons per year of PM_{10} emissions

Ozone: 40 tons per year of volatile organic compounds

Lead: 0.6 ton per year

Fluorides: 3 tons per year

Sulfuric acid mist: 7 tons per year

Hydrogen sulfide (H_2S): 10 tons per year

Total reduced sulfur (including H_2S): 10 tons per year

Reduced sulfur compounds (including H_2S): 10 tons per year

Municipal waste combustor organics (measured as total tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans): $3.2\ 10^{-6}$ megagrams per year ($3.5\ 10^{-6}$ tons per year)

Municipal waste combustor metals (measured as particulate matter): 14 megagrams per year (15 tons per year)

Municipal waste combustor acid gases (measured as sulfur dioxide and hydrogen chloride): 36 megagrams per year (40 tons per year)

Municipal solid waste landfill emissions (measured as nonmethane organic compounds): 45 megagrams per year (50 tons per year)

(2) In reference to a net emissions increase or the potential of a source to emit an air contaminant subject to regulation under North Dakota Century Code chapter 23-25 that paragraph 1 does not list, any emissions rate.

(3) Notwithstanding paragraph 1, any emissions rate or any net emissions increase associated with a major stationary source or major modification, which would construct within ten kilometers [6.21 miles] of a class I area, and have an impact on such area equal to or greater than one $\mu g/m^3$ (twenty-four-hour average).

ii. "Stationary source" means any building, structure, facility, or installation which emits or may emit any air contaminant regulated under North Dakota Century Code chapter 23-25.

jj. "Total suspended particulate (TSP)" means particulate matter as measured by the method described in appendix B of 40 CFR 50.

2. **Significant deterioration of air quality - Area designation and deterioration increment.**

a. The provisions of this chapter apply to those counties or other functionally equivalent areas that are designated as attainment or unclassifiable for any of the national ambient air quality standards.

b. For purposes of this chapter, areas designated as class I, II, or III shall be limited to the following increases in contaminant concentration over the baseline concentration:

Area Designations

Pollutant	Class I ($\mu g/m^3$)	Class II ($\mu g/m^3$)	Class III ($\mu g/m^3$)
Particulate matter:			
PM_{10}, Annual arithmetic mean	4	17	34
PM_{10}, 24-hour maximum	8	30	60
Sulfur dioxide:			
Annual arithmetic mean	2	20	40
24-hour maximum	5	91	182
3-hour maximum	25	512	700
Nitrogen dioxide:			
Annual arithmetic mean	2.5	25	50

For any period other than an annual period, the applicable maximum allowable increase may be exceeded during one such period per year at any receptor site.

Any conflict between an applicable increment and an applicable ambient air quality standard shall be resolved in favor of the more

stringent limitation and the source shall be limited to such more stringent limitation.

c. All of the following areas which were in existence on August 7, 1977, are hereby designated class I areas and may not be redesignated:

(1) The Theodore Roosevelt National Park - north and south units in Billings and McKenzie Counties, and the Theodore Roosevelt Elkhorn Ranch Site in Billings County.

(2) The Lostwood National Wilderness Area in Burke County.

All other areas of the state are hereby designated class II areas but may be redesignated as provided in this subsection.

d. The following areas may be redesignated only as class I or II:

(1) An area which as of August 7, 1977, exceeds ten thousand acres [4046.86 hectares] in size and is a national monument, a national primitive area, a national preserve, a national recreational area, a national wild and scenic river, a national wildlife refuge, a national lakeshore, or seashore.

(2) A national park or national wilderness area established after August 7, 1977, which exceeds ten thousand acres [4046.86 hectares] in size.

e. Exclusions from increment consumption:

(1) The following concentrations shall be excluded in determining compliance with a maximum allowable increase in contaminant concentration:

(a) Concentrations attributable to the increase in emissions from stationary sources which have converted from the use of petroleum products, natural gas, or both, by reason of an order in effect under sections 2(a) and (b) of the Energy Supply and Environmental Coordination Act of 1974 (or any superseding legislation) over the emissions from such sources before the effective date of such order;

(b) Concentrations attributable to the increase in emissions from sources which have converted from using natural gas by reason of natural gas curtailment plan in effect pursuant to the Federal Power Act over the emissions from such sources before the effective date of such plan;

(c) Concentrations of particulate matter attributable to the increase in emissions from construction or other temporary emission-related activities of new or modified sources;

(d) The increase in concentrations attributable to new sources outside the United States over the concentrations attributable to existing sources which are included in the baseline concentration; and

(e) Concentrations attributable to the temporary increase in emissions of sulfur dioxide, particulate matter, or nitrogen oxides from stationary sources which increases have been approved in advance by the department under an approved state implementation plan revision.

(2) No exclusion of such concentrations shall apply more than five years after the effective date of the order to which subparagraph a or b of paragraph 1 refers, whichever is applicable. If both such order and plan are applicable, no such exclusion applies more than five years after the later of such effective dates.

(3) For purposes of excluding concentrations pursuant to subparagraph e of paragraph 1:

(a) The time over which the temporary emissions increase of sulfur dioxide, particulate matter, or nitrogen oxides would occur must be specified. Such time may not exceed two years in duration unless a longer time is approved by the administrator of the United States environmental protection agency.

(b) The time period for excluding certain contributions in accordance with subparagraph a is not renewable.

(c) No emissions increase from a stationary source may:

[1] Impact a class I area or an area where an applicable increment is known to be violated; or

[2] Cause or contribute to the violation of any ambient air quality standards.

(d) The emission levels from the stationary sources effected at the end of the time period specified in accordance with subparagraph a may not exceed

those levels occurring from such sources before the temporary increases in emissions were approved.

f. The class I area increment limitations of the Theodore Roosevelt Elkhorn Ranch Site of the Theodore Roosevelt National Park shall apply to sources or modifications for which complete applications were filed after July 1, 1982. The impact of emissions from sources or modifications for which permits under this chapter have been issued or complete applications have already been filed will be counted against the increments after July 1, 1982.

3. **Stack heights.** The stack height for any source subject to this chapter must meet the requirements of chapter 33-15-18.

4. **Review of new major stationary sources and major modifications.**

a. Applicability. The requirements of this chapter shall apply to any major new stationary source or modification which:

(1) Had not been issued a permit to construct or modify prior to March 1, 1978;

(2) Had not commenced construction prior to March 19, 1979; or

(3) Has discontinued construction for a period of eighteen months or more and has not completed construction within a reasonable time.

Review of these sources or modifications must be conducted in conjunction with the issuance of permits to construct pursuant to section 33-15-14-02.

b. Permits - general.

(1) No source subject to this chapter may be constructed in any area unless:

(a) A permit has been issued for such proposed source in accordance with this chapter setting forth emission limitations or equipment standards for such source which conform to the requirements of this chapter and any conditions necessary to ensure that the proposed source will meet such limits or standards;

(b) The requirements of subdivisions c through k, as applicable, have been met; and

(c) The proposed permit has been subject to a review in accordance with this chapter, the required analysis has

been conducted in accordance with the requirements of this chapter, and the procedures for public participation as defined in subsection 5 have been followed.

(2) Provided that all necessary requirements of this article have been met, permits will be issued on a first-come, first-served basis as determined by the completion date of the applications.

c. Control technology review.

(1) A major stationary source or major modification shall meet all applicable emission limitations under the state implementation plan and all applicable emission standards and standards of performance of this article.

(2) A new major stationary source shall apply best available control technology for each air contaminant subject to regulation under North Dakota Century Code chapter 23-25 that it would have the potential to emit in significant amounts.

(3) A major modification shall apply best available control technology for each air contaminant subject to regulation under North Dakota Century Code chapter 23-25 for which it would result in a significant net emissions increase at the source. This requirement applies to each proposed emissions unit at which a net emissions increase in the air contaminant would occur as a result of a physical change or change in the method of operation in the unit.

(4) For phased construction projects, the determination of best available control technology must be reviewed and modified as appropriate at the latest reasonable time which occurs no later than eighteen months prior to commencement of construction of each independent phase of the project. At such time, the owner or operator of the applicable stationary source may be required to demonstrate the adequacy of any previous determination of best available control technology for the source.

d. Exemptions from impact analysis.

(1) The requirements of subdivisions e, g, and i do not apply to a major stationary source or major modification with respect to a particular air contaminant, if the allowable emissions from the source, or the net emissions increase of that contaminant from the modification:

(a) Would impact no class I area and no area where an applicable increment is known to be violated; and

(b) Would be temporary.

(2) The requirements of subdivisions e, g, and i as they relate to any maximum allowable increase for a class II area do not apply to a major modification at a stationary source that was in existence on March 1, 1978, if the net increase in allowable emissions of each air contaminant regulated under North Dakota Century Code chapter 23-25 from the modification after the application of best available control technology would be less than fifty tons [45359.24 kilograms] per year.

(3) The department may exempt a stationary source or modification from the requirements of subdivision g with respect to monitoring for a particular air contaminant if:

(a) The emissions increase of the air contaminant from the new source or the net emissions increase of the air contaminant from the modification would cause, in any area, air quality impacts less than the following amounts:

Carbon monoxide - 575 $\mu g/m^3$, 8-hour average

Nitrogen dioxide - 14 $\mu g/m^3$, annual average

Particulate matter - 10 $\mu g/m^3$ of PM_{10}, 24-hour average

Sulfur dioxide - 13 $\mu g/m^3$, 24-hour average

Ozone - No de minimus level

Lead - 0.1 $\mu g/m^3$, 3-month average

Mercury - 0.25 $\mu g/m^3$, 24-hour average

Beryllium - 0.001 $\mu g/m^3$, 24-hour average

Fluorides - 0.25 $\mu g/m^3$, 24-hour average

Vinyl chloride - 15 $\mu g/m^3$, 24-hour average

Total reduced sulfur - 10 $\mu g/m^3$, 1-hour average

Hydrogen sulfide - 0.2 $\mu g/m^3$, 1-hour average

Reduced sulfur compounds - 10 $\mu g/m^3$, 1-hour average; or

(b) The concentrations of the air contaminant in the area that the source or modification would affect are less than the concentrations listed in subparagraph a or the air contaminant is not listed in subparagraph a.

(4) The requirements for best available control technology in subdivision c and the requirements for air quality analyses in paragraph 1 of subdivision g do not apply to a particular stationary source or modification that was subject to this chapter if the owner or operator of the source or modification submitted an application for a permit before May 7, 1981, and the department subsequently determines the application as submitted before that date was complete. Instead, the requirements of subdivisions c and h as in effect prior to May 7, 1981, apply to any such source or modification.

(5) The requirements for air quality monitoring in subparagraphs b, c, and d of paragraph 1 of subdivision g do not apply to:

(a) A particular source or modification that was subject to this chapter as in effect prior to May 7, 1981, if the owner or operator of the source or modification submitted an application for a permit under this chapter on or before June 8, 1981, and the department subsequently determined that the application as submitted before that date was complete with respect to the requirements of this chapter other than those in subparagraphs b, c, and d of paragraph 1 of subdivision g and with respect to the requirements for such analyses in paragraph 2 of subdivision g as in effect prior to May 7, 1981. Instead, the requirements of this chapter prior to May 7, 1981, shall apply to any source or modification.

(b) A particular source or modification that was not subject to this chapter as in effect prior to May 7, 1981, if the owner or operator of the source or modification submitted an application for a permit under this chapter on or before June 8, 1981, and the department subsequently determined that the application as submitted before that date was complete, except with respect to the requirements in subparagraphs b, c, and d of paragraph 1 of subdivision g.

(6) The requirements of subdivisions c, e, f, g, h, i, and j and subsections 5 and 6 in their entirety do not apply to a particular major stationary source or major modification, if:

(a) The source or modification would be a major stationary source or major modification only if fugitive emissions, to the extent quantifiable, are considered in calculating the potential to emit of the stationary source or modification and the source does not belong to any of the stationary sources of air contaminants listed in subdivision u of subsection 1 and any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Federal Clean Air Act [Pub. L. 95-95].

(b) The source is a portable stationary source which has previously received a permit under this chapter and:

[1] The owner or operator proposes to relocate the source and emissions of the source at the new location would be temporary.

[2] The emissions from the source would not exceed its allowable emissions.

[3] The emissions from the source would impact no class I area and no area where an applicable increment is known to be violated.

[4] Reasonable notice is given to the department prior to the relocation identifying the proposed new location and the probable duration of operation at the new location. Such notice shall be given to the department not less than ten days in advance of the proposed relocation unless a different time duration is previously approved by the department.

(c) With respect to a particular air contaminant, the owner or operator demonstrates that the source or modification is located in an area designated as nonattainment by the administrator of the United States environmental protection agency, as to that air contaminant, under this article.

(d) The source or modification would be a nonprofit health or nonprofit educational institution, or a major modification would occur at such an institution, and

the governor requests that it be exempt from such requirements.

e. Source impact analysis. The owner or operator of the proposed source or modification shall demonstrate that allowable emission increases from the source or modification, in conjunction with all other applicable emissions increases or reductions (including secondary emissions) from any other sources, will not cause or contribute to air pollution in violation of:

(1) Any ambient air quality standard in any area; or

(2) Any applicable maximum allowable increase over the baseline concentration in any area.

f. Air quality models.

(1) All estimates of ambient concentrations required under this section must be based on the applicable air quality models, data bases, and other requirements specified in the "Guidelines on Air Quality Models" (United States environmental protection agency, office of air quality planning and standards, Research Triangle Park, North Carolina 27711) as supplemented by the "North Dakota Guideline for Air Quality Modeling Analyses" (North Dakota state department of health, division of environmental engineering). These documents are incorporated by reference.

(2) When an air quality impact model specified in the documents incorporated by reference in paragraph 1 is inappropriate, the model may be modified or another model substituted provided:

(a) Any modified or nonguideline model must be subjected to notice and opportunity for public comment under subsection 5.

(b) The applicant must provide to the department adequate information to evaluate the applicability of the modified or nonguideline model. Such information must include methods like those outlined in the "Workbook for the Comparison of Air Quality Models" (United States environmental protection agency, office of air quality planning and standards, Research Triangle Park, North Carolina 27711).

(c) Written approval from the department must be obtained for any modification or substitution prior

to an application being designated complete by the department.

(d) Written approval from the United States environmental protection agency must be obtained for any modification or substitution prior to the granting of a permit under this chapter.

g. Air quality analysis.

(1) Preapplication analysis.

(a) Any application for a permit under this section must contain an analysis of ambient air quality in the area that the major stationary source or major modification would affect for each of the following air contaminants:

[1] For the source, each air contaminant that it would have the potential to emit in a significant amount; and

[2] For the modification, each air contaminant for which it would result in a significant net emissions increase.

(b) With respect to any such air contaminant for which no ambient air quality standard exists, the analysis must contain such air quality monitoring data as the department determines is necessary to assess ambient air quality for that air contaminant in any area that the emissions of that air contaminant would affect.

(c) With respect to any such air contaminant (other than nonmethane hydrocarbons) for which such a standard does exist, the analysis must contain continuous air quality monitoring data gathered for purposes of determining whether emissions of that air contaminant would cause or contribute to a violation of the standard or any maximum allowable increase.

(d) In general, the continuous air quality monitoring data that are required shall have been gathered over a period of at least one year and shall represent at least the year preceding receipt of the application except that if the department determines that a complete and adequate analysis can be accomplished with monitoring data gathered over a period shorter than one year (but not to be less than four months), the

data that are required shall have been gathered over at least that shorter period.

(e) For any application which becomes complete, except as to the requirements of subparagraphs c and d, between June 8, 1981, and February 9, 1982, the data that subparagraph c requires shall have been gathered over at least the period from February 9, 1981, to the date the application becomes otherwise complete, except that:

[1] If the source or modification would have been major for that air contaminant under this chapter as in effect prior to May 7, 1981, any monitoring data shall have been gathered over at least the period required by those rules.

[2] If the department determines that a complete and adequate analysis can be accomplished with monitoring data over a shorter period (not to be less than four months), the data that subparagraph c requires shall have been gathered over at least that shorter period.

[3] If the monitoring data would relate exclusively to ozone and would not have been required under this chapter as in effect prior to May 7, 1981, the department may waive the otherwise applicable requirements of this subparagraph to the extent that the applicant shows that the monitoring data would be unrepresentative of air quality over a full year.

(f) The owner or operator of a proposed stationary source or modification of volatile organic compounds who satisfies all conditions of 40 CFR, part 51, appendix S, section IV may provide postapproved monitoring data for ozone in lieu of providing preconstruction data as required under paragraph 1.

(2) Postconstruction monitoring. The owner or operator of a major stationary source or major modification shall, after construction of the stationary source or modification, conduct such ambient monitoring as the department determines is necessary to determine the effect emissions from the stationary source or modification may have, or are having, on air quality in any area.

(3) Operations of monitoring stations. The owner or operator of a major stationary source or major modification shall meet the requirements of 40 CFR, part 58, appendix B during the operation of monitoring stations for purposes of satisfying subdivision g.

h. Source information. The owner or operator of a proposed major stationary source or major modification shall submit all information necessary to perform any analysis to make any determination required under this article. Such information must include:

(1) A description of the nature, location, design capacity, and typical operating schedule of the proposed source or modification, including specifications and drawings showing the design and plant layout.

(2) A detailed schedule for construction of the source or modification.

(3) A detailed description as to what system of continuous emission reduction is planned by the source or modification, emission estimates, and any other information necessary to determine ~~that~~ best available control technology ~~as specified in the "North Dakota Guidelines for Determining Best Available Control Technology" (North Dakota state department of health, division of environmental engineering). This document is incorporated by reference~~.

(4) The air quality impact of the source or modification, including meteorological and topographical data necessary to estimate such impact.

(5) Information on the air quality impacts and the nature and extent of general commercial, residential, industrial, and other growth which has occurred since the baseline date in the area the source or modification would affect.

i. Additional impact analyses.

(1) The owner or operator shall provide an analysis of the impairment to visibility, (in accordance with chapter 33-15-19) soils and vegetation, and wildlife that would occur as a result of the source or modification and general commercial, residential, industrial, and other growth associated with the source or modification. The owner or operator need not provide an analysis on vegetation or wildlife having no significant commercial or recreational value except for endangered and threatened species as identified by the United States fish and wildlife service.

(2) The owner or operator shall provide an analysis of the air quality impact projected for the area as a result of the general commercial, residential, industrial, and other growth associated with the source or modification.

j. Sources impacting federal class I areas - additional requirements.

(1) Notice to the United States environmental protection agency. The department shall transmit to the administrator of the United States environmental protection agency through the region VIII regional administrator a copy of each permit application relating to a major stationary source or major modification received by the department and provide notice to the administrator of every action related to the consideration of such permit.

(2) Notice to federal land managers. The department shall provide written notice of any permit application for a proposed major stationary source or major modification, the emissions from which may affect a class I area, to the federal land manager and the federal official charged with direct responsibility for management of any lands within any such area. Such notification must include a copy of all information relevant to the permit application and must be given within thirty days of receipt and at least sixty days prior to any public hearing on the application for a permit to construct. Such notification must include an analysis of the proposed source's anticipated impacts on visibility in the federal class I area. The department shall also provide the federal land manager and such federal officials with a copy of the preliminary determination required under subsection 5 and shall make available to them any materials used in making that determination, promptly after the department makes such determination. Finally, the department shall also notify all affected federal land managers within thirty days of receipt of any advance notification of any such permit application.

(3) Denial - impact on air quality-related values. A federal land manager may present to the department, after reviewing the department's preliminary determination required under subsection 5, a demonstration that the emission from an applicable source will have an adverse impact on the air quality-related values (including visibility) of federal mandatory class I lands, notwithstanding that the change in air quality resulting from emissions from such source or modification will not cause or contribute to concentrations which exceed the maximum allowable increases for a class I

area. If the department concurs with such demonstration, the permit may not be issued.

(4) Class I variances.

(a) The owner or operator of a proposed source may demonstrate to the federal land manager that the emissions from such source or modification will have no adverse impact on the air quality-related values of any such lands (including visibility), notwithstanding that the change in air quality resulting from emissions from such source or modification will cause or contribute to concentrations which exceed the maximum allowable increases for a class I area. If the federal land manager concurs with such demonstration and the manager so certifies to the department, the department may issue the permit pursuant to the requirements of subparagraph b; provided, that the applicable requirements of this chapter are otherwise met.

(b) In the case of a permit issued pursuant to subparagraph a, such source or modification shall comply with such emission limitations under such permit as may be necessary to assure that emissions of sulfur dioxide, particulate matter, and nitrogen oxides will not exceed the following maximum allowable increases over the minor source baseline concentration for such contaminants:

	Maximum allowable increase (micrograms per cubic meter)
Particulate matter:	
PM_{10}, Annual arithmetic mean	17
PM_{10}, 24-hour maximum	30
Sulfur dioxide:	
Annual arithmetic mean	20
24-hour maximum	91
3-hour maximum	325
Nitrogen dioxide:	
Annual arithmetic mean	25

(5) Sulfur dioxide variance by governor with federal land manager's concurrence. The owner or operator of a proposed source or modification which cannot be approved

under paragraph 4 may demonstrate to the governor, that the source or modification cannot be constructed by reason of any maximum allowable increase for sulfur dioxide for periods of twenty-four hours or less applicable to any class I area and, in the case of federal mandatory class I areas, that a variance under this clause would not adversely affect the air quality-related values of the area, including visibility. The governor, after consideration of the federal land manager's recommendation, if any, and subject to the federal land manager's concurrence, may, after notice and public hearing, grant a variance from such maximum allowable increase. If such variance is granted, the department shall issue a permit to such source or modification pursuant to the requirements of paragraph 7; provided, that the applicable requirements of this chapter are otherwise met.

(6) Variance by the governor with the president's concurrence. If the governor recommends a variance under this subdivision in which the federal land manager does not concur, the recommendations of the governor and the federal land manager must be transmitted to the president. The president may approve the governor's recommendation if the president finds that such variance is in the national interest. If such a variance is approved, the department shall issue a permit pursuant to the requirements of paragraph 7; provided, that the applicable requirements of this chapter are otherwise met.

(7) Emission limitations for presidential or gubernatorial variances. In the case of a permit issued pursuant to paragraph 5 or 6, the source or modification shall comply with emission limitations under such permit as may be necessary to assure that emissions of sulfur dioxide from such source or modification, during any day on which the otherwise applicable maximum allowable increases are exceeded, will not cause or contribute to concentrations which exceed the following maximum allowable increases over the baseline concentration and to assure that such emissions will not cause or otherwise contribute to concentrations which exceed the otherwise applicable maximum allowable increases for periods of exposure of twenty-four hours or less for more than eighteen days, not necessarily consecutive, during any annual period:

Maximum allowable increase (micrograms per cubic meter)		
Period of exposure	Low terrain areas	High terrain areas
24-hour maximum	36	62
3-hour maximum	130	221

k. Proposed redesignations. If an owner or operator applies for permission to construct pursuant to this chapter and the proposed source or modification would impact on an area which has previously been proposed for redesignation to a more stringent class by the department, an Indian governing body, or another state, or the state or Indian governing body has announced such consideration, approval may not be granted until the proposed redesignation has been acted upon. However, approval must be granted if, in the department's judgment, the proposed source would not violate the increments that would be applicable if the redesignation is approved. The department shall withhold approval under this subdivision only so long as another state or Indian governing body is actively and expeditiously proceeding toward redesignation.

If an owner or operator has applied for permission to construct pursuant to this chapter and whose application has been deemed complete by the department prior to the public announcement of a proposed redesignation of an area to a more stringent class and if such facility would impact on the area proposed for redesignation, the application shall be processed considering the classification of the area which existed at the time the application was deemed complete.

5. **Public participation.**

a. Within thirty days after receipt of an application to construct a source or modification subject to this chapter, or any addition to such application, the department shall advise the applicant as to the completeness of the application or of any deficiency in the application or information submitted. In the event of such a deficiency, the date of receipt of the application, for the purpose of this chapter, shall be the date on which all required information to form a complete application is received by the department.

b. Within one year after receipt of a completed application, the department shall:

(1) Make a preliminary determination whether the source should be approved, approved with conditions, or disapproved pursuant to the requirements of this chapter.

(2) Make available in at least one location in each region in which the proposed source or modification would be constructed, a copy of all materials submitted by the applicant, a copy of the department's preliminary determination, and a copy or summary of other materials, if any, considered by the department in making a preliminary determination.

(3) Notify the public, by prominent advertisement in newspapers of general circulation in each region in which the proposed source or modification would be constructed, of the application, the preliminary determination, the degree of increment consumption that is expected from the source or modification, and the opportunity for comment at a public hearing as well as written public comment on the information submitted by the owner or operator and the department's preliminary determination on the approvability of the source.

(4) Send a copy of the notice required in paragraph 3 to the applicant, the United States environmental protection agency administrator, and to officials and agencies having cognizance over the locations where the source or modification will be situated as follows: local air pollution control agencies, the chief executive of the city and county where the source or modification would be located; any comprehensive regional land use planning agency; and any state, federal land manager, or Indian governing body whose lands may be significantly affected by emissions from the source or modification.

(5) Hold a public hearing whenever, on the basis of written requests, a significant degree of public interest exists or at its discretion when issues involved in the permit decision need to be clarified. A public hearing would be held during the public comment period for interested persons, including representatives of the United States environmental protection agency administrator, to appear and submit written or oral comments on the air quality impact of the source or modification, alternatives to the source or modification, the control technology required, and other appropriate considerations.

(6) Consider all public comments submitted in writing within a time specified in the public notice required in paragraph 3 and all comments received at any public hearing conducted pursuant to paragraph 5 in making its final decision on the approvability of the application. No later than ten days after the close of the public comment period, the applicant may submit a written response to any comments submitted by the public. The department shall consider the applicant's response in making its final decision. All comments must be made available for public inspection in the same locations where the department made available preconstruction information relating to the source or modification.

(7) Make a final determination whether the source should be approved, approved with conditions, or disapproved pursuant to the requirements of this chapter.

(8) Notify the applicant in writing of the department's final determination. The notification must be made available for public inspection in the same locations where the department made available preconstruction information and public comments relating to the source or modification.

6. **Source obligation.**

a. Any owner or operator who constructs or operates a stationary source or modification not in accordance with the application, submitted pursuant to subsection 4 or with the terms of any permit to construct; or any owner or operator of a stationary source or modification subject to this chapter who commences construction after the effective date of this chapter without applying for and receiving a permit to construct hereunder, shall be subject to enforcement action under North Dakota Century Code section 23-25-10.

b. A permit to construct shall become invalid if construction is not commenced within eighteen months after receipt of such permit, if construction is discontinued for a period of eighteen months or more, or if construction is not completed within a reasonable time. The department may extend the eighteen-month period upon a satisfactory showing that an extension is justified. This provision does not apply to the time period between construction of the approved phases of a phased construction project; each phase must commence construction within eighteen months of the projected and approved commencement date. In cases of major construction projects involving long lead times and substantial financial commitments, the department may provide by a condition to the permit a time period greater than eighteen months when such time extension is supported by sufficient documentation by the applicant.

c. A permit to construct does not relieve any owner or operator of the responsibility to comply fully with the applicable provisions of the state implementation plan and any other requirements under local, state, or federal law.

d. At such time that a particular source or modification becomes a major stationary source or modification solely by virtue of a relaxation in any enforceable limit which was established after May 7, 1980, on the capacity of the source or modification otherwise to emit an air contaminant, such as a restriction on hours of operation, then the requirements of subdivisions c,

e, f, g, h, i, and j and the requirements of this subsection and subsections 5 and 7 shall apply to the source or modification as though construction had not yet commenced on the source or modification.

7. **Innovative control technology.**

a. An owner or operator of a proposed major stationary source or major modification may request the department in writing to approve a system of innovative control technology.

b. The department shall, with the consent of the governors of all affected states, determine that the source or modification may employ a system of innovative control technology, if:

(1) The proposed control system would not cause or contribute to an unreasonable risk to public health, welfare, or safety in its operation or function.

(2) The owner or operator agrees to achieve a level of continuous emissions reduction equivalent to that which would have been required under paragraph 2 of subdivision c of subsection 4 by a date specified by the department. Such date may not be later than four years from the time of startup or seven years from permit issuance.

(3) The source or modification would meet the requirements of subdivisions c and e of subsection 4 based on the emissions rate that the stationary source employing the system of innovative control technology would be required to meet on the date specified by the department.

(4) The source or modification would not before the date specified by the department:

(a) Cause or contribute to a violation of an applicable ambient air quality standard; or

(b) Impact any area where an applicable increment is known to be violated.

(5) The provisions of subdivision j of subsection 4, relating to class I areas, have been satisfied with respect to all periods during the life of the source or modification.

(6) All other applicable requirements including those for public participation have been met.

c. The department shall withdraw any approval to employ a system of innovative control technology made under this section, if:

(1) The proposed system fails by the specified date to achieve the required continuous emissions reduction rate;

(2) The proposed system fails before the specified date so as to contribute to an unreasonable risk to public health, welfare, or safety; or

(3) The department decides at any time that the proposed system is unlikely to achieve the required level of control or to protect the public health, welfare, or safety.

d. If a source or modification fails to meet the required level of continuous emission reduction within the specified time period or the approval is withdrawn in accordance with subdivision c, the department may allow the source or modification up to an additional three years to meet the requirement for the application of best available control technology through use of a demonstrated system of control.

History: Amended effective July 1, 1982; October 1,1987; January 1, 1989; June 1, 1990; June 1, 1992; March 1, 1994; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03, 23-25-04.1
Law Implemented: NDCC 23-25-03, 23-25-04.1

33-15-21-08.1. Permits. The provisions of title 40, Code of Federal Regulations, part 72, as they exist on ~~August 1, 2000~~ January 31, 2002, for purposes of implementing an acid rain program that meets the requirements of title IV of the federal Clean Air Act, are incorporated into this chapter by reference. The term "administrator" means the department except for those duties that cannot be delegated to the department. For those duties that cannot be delegated, "administrator" means the administrator of the United States environmental protection agency. If the provisions or requirements of title 40, Code of Federal Regulations, part 72, conflict with or are not included in section 33-15-14-06, the provisions of part 72 shall apply and take precedence.

History: Effective June 1, 2001; amended effective March 1, 2003.
General Authority: NDCC 23-25-03, 23-01-04.1
Law Implemented: NDCC 23-25-03, 23-25-04, 23-25-04.1

33-15-21-09. Continuous emissions monitoring.

1. **General.** The monitoring, recordkeeping, and reporting of sulfur dioxide, nitrogen oxides, and carbon dioxide emissions, volumetric flow, and opacity data from affected units under the acid rain program shall be conducted in accordance with title 40, Code of Federal Regulations, part 75, as it exists on ~~August 1, 2000~~ January 31, 2002.

2. **Exceptions.** Those portions of title 40, Code of Federal Regulations, part 75, that are controlled and administered completely by the United States environmental protection agency will not be enforced by the state. This should not be construed as precluding the United States environmental protection agency from exercising its statutory authority under the Clean Air Act, as amended, or an affected source from complying with the authority or the requirements of the federal acid rain program.

History: Effective December 1, 1994; amended effective June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03, 23-25-04, 23-25-04.1

33-15-21-10. Acid rain nitrogen oxides emission reduction program. Title 40, Code of Federal Regulations, part 76 and its appendices, as they exist on ~~August 1, 2000~~ January 31, 2002, are incorporated into this chapter by reference.

History: Effective April 1, 1998; amended effective June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-01-04.1, 23-25-03

CHAPTER 33-15-22

33-15-22-01. Scope. The subparts and appendices of title 40, Code of Federal Regulations, part 63, as they exist on ~~August 1, 2000~~ January 31, 2002, which are listed in section 33-15-22-03 are incorporated into this chapter by reference. Any changes to an emissions standard are listed below the title of the standard.

History: Effective December 1, 1994; amended effective August 1, 1995; January 1, 1996; September 1, 1997; April 1, 1998; September 1, 1998; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

33-15-22-03. Emissions standards.

Subpart A - General provisions.

Subpart B - Requirements for control technology determinations for major sources in accordance with Federal Clean Air Act sections 112(g) and 112(j).

*Sections 63.42(a) and 63.42(b) are deleted in their entirety.

Subpart C - List of hazardous air pollutants, petitions process, lesser quantity designations, and source category list.

Subpart D - Regulations governing compliance extensions for early reductions of hazardous air pollutants.

Subpart F - National emissions standards for organic hazardous air pollutants from the synthetic organic chemical manufacturing industry.

Subpart G - National emissions standards for organic hazardous air pollutants from synthetic organic chemical manufacturing industry for process vents, storage vessels, transfer operations, and wastewater.

Subpart H - National emissions standards for organic hazardous air pollutants for equipment leaks.

Subpart I - National emissions standards for organic hazardous air pollutants for certain processes subject to the negotiated regulation for equipment leaks.

Subpart M - National perchloroethylene air emissions standards for drycleaning facilities.

Subpart N - National emissions standards for chromium emissions from hard and decorative chromium electroplating and chromium anodizing tanks.

Subpart O - Ethylene oxide emissions standards for sterilization facilities.

Subpart Q - National emissions standards for hazardous air pollutants for industrial process cooling towers.

Subpart R - National emissions standards for gasoline distribution facilities (bulk gasoline terminals and pipeline breakout stations).

Subpart T - National emissions standards for halogenated solvent cleaning.

Appendix A to subpart T - Test of solvent cleaning procedures.

Appendix B to subpart T - General provisions applicability to subpart T.

Subpart W - National emissions standards for hazardous air pollutants for epoxy resins production and non-nylon polyamides production.

Table 1 to subpart W - General provisions applicability to subpart W.

Subpart X - National emissions standards for hazardous air pollutants from secondary lead smelting.

Subpart CC - National emissions standards for hazardous air pollutants from petroleum refineries.

Subpart EE - National emissions standards for magnetic tape manufacturing operations.

Subpart GG - National emissions standards for aerospace manufacturing and rework facilities.

Subpart HH - National emissions standards for hazardous air pollutants from oil and natural gas production facilities.

Subpart JJ - National emissions standards for wood furniture manufacturing operations.

Subpart KK - National emissions standards for the printing and publishing industry.

Table 1 to subpart KK - Applicability of general provisions to subpart KK.

Appendix A to subpart KK - Data quality objective and lower confidence limit approaches for alternative capture efficiency protocols and test methods.

Subpart OO - National emissions standards for tanks - Level 1.

Subpart PP - National emissions standards for containers.

Subpart QQ - National emissions standards for surface impoundments.

Subpart RR - National emissions standards for individual drain systems.

Subpart SS - National emissions standards for closed vent systems, control devices, recovery devices, and routing to a fuel gas system or a process.

Subpart TT - National emissions standards for equipment leaks - Control level 1.

Subpart UU - National emissions standards for equipment leaks - Control level 2 standards.

Subpart VV - National emissions standards for oil-water separators and organic water separators.

Subpart WW - National emissions standards for storage vessels (tanks) - Control level 2.

Subpart YY - National emissions standards for hazardous air pollutants for source categories: generic maximum achievable control technology standards.

~~Subpart RRR - National emissions standards for hazardous air pollutants for secondary aluminum production.~~

Subpart HHH - National emissions standards for hazardous air pollutants from natural gas transmission and storage facilities.

Subpart RRR - National emission standards for hazardous air pollutants for secondary aluminum production.

Table 1 to Subpart RRR - Emission standards for new and existing affected sources.

Table 2 to Subpart RRR - Summary of operating requirements for new and existing affected sources and emission units.

Table 3 to Subpart RRR - Summary of monitoring requirements for new and existing affected sources and emission units.

Appendix A to Subpart RRR - General provisions applicability to subpart RRR.

Subpart CCCC - National emission standards for hazardous air pollutants: manufacturing of nutritional yeast.

Subpart GGGG - National emission standards for hazardous air pollutants: solvent extraction for vegetable oil production.

Appendix A to part 63 - Test methods.

Appendix B to part 63 - Sources defined for early reduction provisions.

Appendix C to part 63 - Determination of the fraction biodegraded (f_{bio}) in a biological treatment unit.

Appendix D to part 63 - Alternative validation procedure for environmental protection agency waste and wastewater methods.

Authority: 42 U.S.C. 7401 et seq.

History: Effective December 1, 1994; amended effective August 1, 1995; January 1, 1996; September 1, 1997; April 1, 1998; September 1, 1998; June 1, 2001; March 1, 2003.
General Authority: NDCC 23-25-03
Law Implemented: NDCC 23-25-03

TITLE 45

INSURANCE COMMISSIONER

JANUARY 2003

ARTICLE 45-07

CREDIT INSURANCE

CHAPTER 45-07-01
CREDIT LIFE AND CREDIT ACCIDENT

[Repealed effective January 1, 2003]

CHAPTER 45-07-01.1
CONSUMER CREDIT INSURANCE

45-07-01.1-01. Definitions. As used in this chapter:

1. "Affiliate" has the same meaning as defined in North Dakota Century Code section 26.1-10-01.

2. "Control" has the same meaning as defined in North Dakota Century Code section 26.1-10-01.

3. "Evidence of individual insurability" means a statement furnished by the debtor, as a condition of insurance becoming effective, that relates specifically to the health status or to the health or medical history of the debtor.

4. "Loss ratio" means incurred claims divided by earned premiums.

5. "Preexisting condition" means any condition for which the insured debtor received medical advice, consultation, or treatment within six months before the effective date of coverage.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-02. Rights and treatment of debtors.

1. **Termination of group consumer credit insurance policy.**

   a. If a debtor is covered by a group consumer credit insurance policy providing for the payment of single premiums to the insurer, or any other premium payment method which prepays coverage beyond

one month, then provision shall be made by the insurer that in the event of termination of the policy for any reason, insurance coverage with respect to any debtor insured under the policy shall be continued for the entire period for which the premium has been paid.

b. If a debtor is covered by a group consumer credit insurance policy providing for the payment of premiums to the insurer on a monthly basis, then the policy shall provide that, in the event of termination of the policy, termination notice shall be given to the insured debtor at least thirty days prior to the effective date of termination except when replacement of the coverage by the same or another insurer in the same or greater amount takes place without lapse of coverage. The insurer shall provide or cause to be provided this required information to the debtor.

2. **Remittance of premiums.** If the creditor adds identifiable insurance charges or premiums for consumer credit insurance to the debt, and any direct or indirect finance, carrying, credit, or service charge is made to the debtor on the insurance charges or premiums, the creditor must remit and the insurer shall collect the premium within sixty days after it is added to the debt.

3. **Refinancing of the debt.** If the debt is discharged due to refinancing prior to the scheduled maturity date, the insurance in force shall be terminated before any new insurance may be issued in connection with the refinanced debt. In all cases of termination prior to scheduled maturity, a refund of all unearned premium or unearned insurance charges paid by the debtor shall be paid or credited to the debtor as provided in section 45-07-01.1-08. In any refinancing of the debt, the effective date of the coverage as respects any policy provision shall be deemed to be the first date on which the debtor became insured under the policy with respect to the debt which was refinanced, at least to extent of the amount and term of the debt outstanding at the time of refinancing of the debt.

4. **Maximum aggregate provisions.** A provision in an individual policy or group certificate which sets a maximum limit on total claim payments must apply only to that individual policy or group certificate.

5. **Prepayment of debt.** If a debtor prepays the debt in full, then any consumer credit insurance covering the debt shall be terminated and an appropriate refund of the consumer credit insurance premium shall be paid or credited to the debtor in accordance with section 45-07-01.1-08. However, if the prepayment is a result of death or any other lump sum consumer credit insurance payment, no refund shall be required for the coverage under which the lump sum was paid. If a claim under credit accident and health coverage or credit unemployment coverage is in progress at the time of prepayment, the

amount of refund may be determined as if the prepayment did not occur until the payment of benefits terminates. No refund need be paid during any period of disability for which credit accident and health benefits are payable or during any period of unemployment for which credit unemployment benefits are payable. A refund shall be computed as if prepayment occurred at the end of the disability period or at the end of the unemployment period.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-03. Determination of reasonableness of benefits in relation to premium charge.

1. Benefits provided by consumer credit insurance policies must be reasonable in relation to the premium charged. Premium rates charged for credit life or disability satisfy this requirement if the premium rate charged develops or may reasonably be expected to develop a loss ratio of not less than forty-five percent. With the exception of deviations approved under section 45-07-01.1-10, the rates shown in sections 45-07-01.1-04 and 45-07-01.1-05, as adjusted pursuant to section 45-07-01.1-09, shall be presumed to satisfy this standard. Anticipated losses that develop or are expected to develop a loss ratio of not less than forty-five percent shall be presumed reasonable. Any insurer filing a deviation in accordance with section 45-07-01.1-10 must satisfy the sixty percent loss ratio standard on its total consumer credit insurance business, including that of affiliated insurers, for each type of insurance defined in North Dakota Century Code section 26.1-37-02 for which the deviation is being filed.

2. Premium rates charged for credit unemployment or credit property satisfy this requirement if anticipated losses are expected to develop a loss ratio of no less than forty-five percent.

3. Nonstandard coverage. If any insurer files for approval of any form providing coverage different than that described in sections 45-07-01.1-04 through 45-07-01.1-06, the insurer shall demonstrate to the satisfaction of the commissioner that the premium rates to be charged for such coverage are:

   a. Reasonably expected to develop a loss ratio of not less than sixty percent; or

   b. Actuarially consistent with the rates used for standard coverages.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-04. Credit life insurance rates.

1. **Premium rate.** Subject to the conditions and requirements in subsection 2 and section 45-07-01.1-10, the prima facie rates shown below are considered to meet the requirements of section 45-07-01.1-03 and may be used without filing additional actuarial support.

   a. Monthly outstanding balance basis: Sixty-two cents per month per one thousand dollars of outstanding insured debt on single life insurance and one dollar five cents per month per one thousand dollars of outstanding insured debt on joint life insurance if premiums are payable on a monthly outstanding balance basis.

   b. Single premium basis: If the premium is charged on a single premium basis, the rate shall be computed according to the following formula or according to a formula approved by the commissioner which produces rates substantially the same as those produced by the following formula:

$$S_p = \sum_{t=1}^{10} \left(\frac{{}_nO_p}{I_i} \times I_t \times (v^{t-1}) \right)$$

$$v = \frac{1}{1 + (dis)}$$

   S_p = Single premium per one hundred dollars of initial consumer credit life insurance coverage.

   O_p = Sixty-two cents, the prima facie consumer credit life insurance premium rate for monthly outstanding balance coverage from subdivision a.

   I_t = The scheduled amount of insurance for month t.

   I_i = Initial amount of insurance. For a net insurance policy, I_i equals the initial principal balance of the loan.

   dis = .0028, representing an annual discount rate of three percent for interest plus four-tenths percent for mortality.

   n = The number of months in the term of the insurance.

   c. If the benefits provided are other than those described in the introduction to this subsection, premium rates for such

benefits shall be actuarially consistent with the rates provided in subdivisions a and b.

d. If life coverage is sold on a joint basis involving two people, the factor for calculating the rate is 1.7.

2. **Conditions and requirements.**

a. Coverage may exclude death resulting from:

(1) War or any act of war;

(2) Suicide within one year after the effective date of the coverage;

(3) A preexisting condition that causes or substantially contributes to death within twelve months of the effective date of coverage; or

(4) Terminal illness with a life expectancy of twelve months or less which was diagnosed prior to the effective date of coverage.

b. The effective date of coverage for that part of the insurance attributable to a different advance or a charge to the plan account is the date on which the advance or charge occurs.

c. An age restriction may be included provided coverage continues until at least age seventy.

d. Guaranteed issue amount. An insurer must issue an amount up to five thousand dollars without regard to a debtor's or creditor's health status. An amount in excess of five thousand dollars may be denied based upon the company's underwriting determination. An insurer may apply the exclusions set forth in subdivision a to the entire amount.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-05. Credit accident and health insurance rates.

1. Premium rate. Subject to the conditions and requirements in subsection 5 and section 45-07-01.1-10, the prima facie rates shown below are considered to meet the requirements of section 45-07-01.1-03 and may be used without filing additional actuarial support.

a. If premiums are payable on a single premium basis for the duration of the coverage, the prima facie rate per one hundred dollars of initial insured debt for single accident and health insurance is as set forth in the table below (rates for monthly periods other than those listed shall be interpolated or extrapolated):

Number of Equal Monthly Installments	After Fourteenth Day of Disability, Retroactive to Fire Day of Disability	After Fourteenth Day of Disability	After Thirtieth Day of Disability, Retroactive to First Day of Disability	After Thirtieth Day of Disability
6	$1.31	$.83	$1.05	$.55
12	1.88	1.30	1.51	.94
24	2.54	1.85	2.03	1.39
36	3.01	2.23	2.38	1.70
48	3.40	2.56	2.65	1.94
60	3.74	2.83	2.89	2.16
72	4.00	3.06	3.06	2.32
84	4.17	3.24	3.18	2.43
96	4.30	3.38	3.27	2.51
108	4.40	3.50	3.34	2.58
120	4.47	3.60	3.40	2.62

b. If premiums are paid on the basis of a premium rate per month per thousand of outstanding insured gross debt, these premiums shall be computed according to the following formula or according to a formula approved by the commissioner which produces rates actuarially consistent with the single premium rates in subdivision a of subsection 1:

$$OP_n = \frac{10\ SP_n}{\sum_{t=1}^{n} \left(v^{t-1} \times (n-t+1)\right)}$$

where $v = \frac{1}{1 + (dis)}$

Where SP_n = Single premium rate per one hundred dollars of initial insured debt repayable in n equal monthly installments as shown in subdivision a.

OP_n = Monthly outstanding balance premium rate per one thousand dollars.

n = The number of months in the term of the insurance.

dis = .0025, representing an annual discount rate of three percent for interest.

c. If the coverage provided is a constant maximum indemnity for a given period of time, the actuarial equivalent of subdivisions a and b shall be used.

d. If the coverage provided is a combination of a constant maximum indemnity for a given period of time after which the maximum indemnity begins to decrease in even amounts per month, an appropriate combination of the premium rate for a constant maximum indemnity for a given period of time and the premium rate for a maximum indemnity which decreases in even amounts per month shall be used.

e. The outstanding balance rate for credit accident and health insurance may be either a term-specified rate or may be a single composite term outstanding balance rate.

2. Subject to the conditions and requirements in subsection 5 and section 45-07-01.1-10, the prima facie rates for credit accident and health insurance shown below are considered to meet the requirements of section 45-07-01.1-03 in the situation where the insurance is written on an open-end loan. These prima facie rates and the formulae used to calculate them may be used without filing additional actuarial support. Other formulae to convert from a closed-end credit rate to an open-end credit rate may be used if approved by the commissioner.

a. If the maximum benefit of the insurance equals the net debt on the date of disability, the term of the loan is calculated according to the formula: 1/(minimum payment percent). The prima facie rate is determined by applying the calculated term to the rates shown in subsection 1. A composite minimum payment percentage may be used in place of the minimum payment percentage for a specific credit transaction.

b. If the maximum benefit of the insurance equals the outstanding balance of the loan on the date of disability plus any interest accruing on that amount during disability, the term of the insurance (n) is estimated by using the following formula:

$n = 1n\{1-(1000i/x)\}/1n(v)$

where:

i = interest rate on the account or a composite interest rate used for the type of policy;

x = monthly payment per one thousand dollars of coverage consistent with the term calculated above; and

$v = 1/(1 + i)$.

The calculated value of the term is used to look up an initial rate in subsection 1. The final prima facie rate is calculated by multiplying the initial rate by:

the adjustment n/an

where:

n is the term calculated above; and

$a_{\overline{n}} = (1 - v)/i$.

3. If the accident and health coverage is sold on a joint basis involving two people, the factor for calculating the rate is 1.8.

4. If the benefits provided are other than those described in subsection 1 or 2, rates for those benefits shall be actuarially consistent with rates provided in subsections 1 and 2.

5. The premium rates in subsection 1 shall apply to contracts providing credit accident and health insurance and that contain the provisions below:

   a. Coverage may be excluded for disabilities resulting from:

      (1) Normal pregnancy;

      (2) War or any act of war;

      (3) Elective surgery;

      (4) Intentionally self-inflicted injury;

(5) Sickness or injury caused by or resulting from the use of alcoholic beverages or narcotics, including hallucinogens, unless they are administered on the advice of and taken as directed, by a licensed physician other than the insured;

(6) Flight in any aircraft other than a commercial scheduled aircraft; or

(7) A preexisting condition from which the insured debtor becomes disabled within six months after the effective date of coverage.

b. For the preexisting condition exclusion above, the effective date of coverage for that part of the insurance attributable to a different advance or a charge to the plan account may be the date on which the advance or charge occurs.

c. A definition of disability providing that for the first twelve months of disability, total disability shall be defined as the inability to perform the essential functions of the insured's own occupation. Thereafter, it shall mean the inability of the insured to perform the essential functions of any occupation for which the insured is reasonably suited by virtue of education, training, or experience.

d. No employment requirement more restrictive than one requiring that the debtor be employed full time on the effective date of coverage and for at least twelve consecutive months prior to the effective date of coverage. "Full time" means a regular workweek of not less than thirty hours.

e. An age restriction providing that no insurance will become effective on debtors on or after the attainment of age sixty-six and that all insurance will terminate upon attainment by the debtor of age sixty-six.

f. A daily benefit of not less than one-thirtieth of the monthly benefit payable under the policy.

g. Guaranteed issue. An insurer must issue a benefit amount up to five thousand dollars without regard to a debtor's or creditor's health status. A credit accident and health insurance benefit amount in excess of five thousand dollars may be denied based upon the company's underwriting determination. The benefit amount for credit accident and health insurance is defined as

the monthly disability payment times the maximum number of payments payable.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-06. Credit unemployment insurance rates.

1. Each insurer filing rates for credit unemployment insurance shall include in its rate filing with the commissioner the appropriate rate formula upon which its rates are based, including a provision for anticipated losses. Anticipated losses that develop or are expected to develop a loss ratio of not less than forty-five percent shall be presumed reasonable. Anticipated losses may include an amount for fluctuation in loss due to catastrophe based on the experience of at least the latest nine policy years or as long as the company has been writing this line of business. If coverage is sold on a joint basis involving two people, the factor for calculating the rate is 1.8.

2. Credit unemployment insurance policies must contain benefits at least as favorable to insureds as the provisions below:

   a. Coverage for unemployment for any reason, except that coverage may be excluded for:

      (1) Voluntary forfeiture of salary, wage, or other employment income;

      (2) Resignation;

      (3) Retirement;

      (4) General strike;

      (5) Illegal walkout;

      (6) War;

      (7) Separation from the military;

      (8) Willful misconduct or criminal misconduct or unlawful behavior; and

      (9) Disability caused by injury, sickness, or pregnancy.

   b. For credit unemployment insurance which provides for a monthly benefit in the event of unemployment, benefits must start after a waiting period of not longer than thirty days but need not be

retroactive to the first day of unemployment and must have a maximum benefit period that is no shorter than six months.

3. Credit unemployment insurance policies may not contain eligibility requirements more restrictive than the restrictions below:

   a. Exclusion from qualification for coverage:

      (1) Self-employed individuals;

      (2) Workers in seasonal or temporary jobs, defined as jobs designed to last six consecutive months or less; and

      (3) Debtors who have been notified either orally or in writing of any layoff or of employment termination either now or within the next sixty days.

      This exclusion must be disclosed to all prospective insureds.

   b. No employment requirement more restrictive than one requiring that the debtor be employed full time on the effective date of coverage for at least twelve consecutive months prior to the effective date of coverage. "Full time" means a regular workweek of not less than thirty hours.

   c. An age restriction providing that no insurance will become effective on debtors on or after the attainment of age sixty-six and that all insurance will terminate upon attainment by the debtor of age sixty-six.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-07. Credit property insurance rates.

1. Each insurer filing rates for credit property insurance shall include in its rate filing with the commissioner the appropriate rate formula upon which its rates are based, including a provision for anticipated losses. Anticipated losses that develop or are expected to develop a loss ratio of no less than forty-five percent shall be presumed to be reasonable. Anticipated losses may include an amount for fluctuation in loss due to catastrophe.

2. Credit property rates must provide for at a minimum the following coverages found in the standard fire policy and extended coverage

endorsement: fire, lightning, riot, riot attending a strike, civil commotion, smoke, aircraft and vehicle damage, windstorm, hail, and explosion.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-08. Refund formulas.

1. In the event of termination, no charge for consumer credit insurance may be made for the first fifteen days of a month and a full month may be charged for sixteen days or more of a month.

2. The requirements of the consumer credit insurance law that refund formulas be filed with the commissioner shall be considered fulfilled if the refund formulas are set forth in the individual policy or group certificate filed with the commissioner.

3. No refund of five dollars or less need be made.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-09. Experience reports and adjustment of prima facie rates.

1. The commissioner will, on a triennial basis, beginning January 1, 2006, review the loss ratio standards set forth in section 45-07-01.1-03 and the prima facie rates set forth in sections 45-07-01.1-04 and 45-07-01.1-05 and determine therefrom the rate of expected claims on a statewide basis, compare such rate of expected claims with the rate of actual claims for the preceding three years determined from the incurred claims and earned premiums at prima facie rates reported in the annual statement supplement or other available source, and publish the adjusted actual statewide prima facie rates to be used by insurers during the next triennium. The rates will reflect the difference between:

   a. Actual claims based on experience; and

   b. Expected claims based on the loss ratio standards set forth in section 45-07-01.1-03 applied to the prima facie rates set forth in sections 45-07-01.1-04 and 45-07-01.1-05.

2. The commissioner will, on a triennial basis, review the discount rates for interest included in the formulae in subsection 1 of section

45-07-01.1-04 and subsection 1 of section 45-07-01.1-05 and has the discretion to adjust those discount rates.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-10. Use of rates.

1. **Use of prima facie rates.** An insurer that files rates or has rates on file that are equivalent to the prima facie rates shown in sections 45-07-01.1-04 and 45-07-01.1-05, to the extent adjusted pursuant to section 45-07-01.1-09, may use those rates without further proof of their reasonableness.

2. **Use of rates higher than prima facie rates.** An insurer may file for approval of and use rates that are higher than the prima facie rates shown in sections 45-07-01.1-04 and 45-07-01.1-05, to the extent adjusted pursuant to section 45-07-01.1-09, as long as the filed rates are consistent with the provisions of section 45-07-01.1-03.

   If rates higher than the prima facie rates shown in sections 45-07-01.1-04 and 45-07-01.1-05, to the extent adjusted pursuant to section 45-07-01.1-09, are filed for approval, the filing shall specify the account or accounts to which the rates apply. The rates may be:

   a. Applied uniformly to all accounts of the insurer;

   b. Applied on an equitable basis approved by the commissioner to only one or more accounts of the insurer for which the experience has been less favorable than expected; or

   c. Applied according to a case-rating procedure on file with the commissioner.

3. **Approval period of deviated rates.**

   a. A rate that deviates from a prima facie rate will be in effect for a period of time not longer than the experience period used to establish the rate, i.e., one year, two years, or three years. An insurer may file for a new rate before the end of a rate period but not more often than once during any twelve-month period.

   b. Notwithstanding the provision of subsection 1, if an account changes insurers, the rate approved to be used for the account by the prior insurer is the maximum rate that may be used by the succeeding insurer for the remainder of the rate approval period approved for the prior insurer or until a new rate is approved for use on the account, if sooner.

4. **Use of rates lower than filed rates.** An insurer may at any time use a rate for an account that is lower than its filed rate without notice to the commissioner.

5. **Glossary of terms and definitions.**

   a. "Experience" means "earned premiums" and "incurred losses" during the experience period.

   b. "Experience period" means the most recent period of time for which earned premiums and incurred losses are reported but not for a period longer than three full years.

   c. "Incurred losses" means total claims paid during the experience period, adjusted for the change in claim reserve.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-11. Supervision of consumer credit insurance operations.

1. Each insurer transacting credit insurance in this state shall be responsible for conducting a thorough periodic triennial review of creditors with respect to their credit insurance business with such creditors to assure compliance with the insurance laws of this state and the regulation promulgated by the commissioner.

2. Written records of such reviews shall be maintained by the insurer for review by the commissioner.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-12. Prohibited transactions. The following practices, when engaged in by insurers in connection with the sale or placement of credit insurance, or as an inducement thereto, shall constitute unfair methods of competition and shall be subject to the Unfair Trade Practices Act of this state.

1. The offer or grant by an insurer to a creditor of any special advantage or any service not set out in either the group insurance contract or in the agency contract, other than the payment of agent's commissions;

2. Agreement by an insurer to deposit with a bank or financial institution money or securities of the insurer with the design or intent that the same shall affect or take the place of a deposit of money or securities which otherwise would be required of the creditor by the bank or financial

institution as a compensating balance or offsetting deposit for a loan or other advancement; and

3. Deposit by an insurer of money or securities without interest or at a lesser rate of interest than is currently being paid by the creditor, bank, or financial institution to other depositors of like amounts for similar durations. This subsection shall not be construed to prohibit the maintenance by an insurer of such demand deposits or premium deposit accounts as are reasonably necessary for use in the ordinary course of the insurer's business.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

45-07-01.1-13. Severability. If any provision or clause of this chapter or the application thereof to any person or situation is held invalid, such invalidity shall not affect any other provision or application of the chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are declared severable.

History: Effective January 1, 2003.
General Authority: NDCC 26.1-37-15
Law Implemented: NDCC 26.1-37

TITLE 48

STATE BOARD OF ANIMAL HEALTH

MAY 2003

CHAPTER 48-02-01

48-02-01-01. Importation - All livestock - Certificate of veterinary inspection required - Exemptions. ~~All~~ Except as otherwise provided in this section or chapter, all imported domestic animals ~~and nontraditional livestock~~ must be accompanied by an official certificate of veterinary inspection~~, except~~. But domestic animals originating directly from a producer's premises, not diverted en route, and consigned to an auction market, or ~~stockyards~~ stockyard approved by the board ~~of animal health~~; and livestock consigned to a state or federally inspected slaughtering establishment are exempt from the requirement. Prior to importation, the board may grant exceptions to the certificate of veterinary inspection requirement, if in the opinion of the board, the animals are free of contagious and infectious diseases. In addition to the disease testing, treatment, vaccination, or identification requirements of this chapter, the state veterinarian may require additional disease testing, treatment, vaccination, or identification if the state veterinarian has reason to believe that other health risks are present.

History: Amended effective September 1, 1988; October 1, 1998; May 1, 2003.
General Authority: NDCC 36-01-08
Law Implemented: NDCC 36-01-08

48-02-01-02. General - Importation permits.

1. No animal or poultry that is infected, or recently exposed to any infectious or transmissible disease, shall be imported. ~~A certificate of veterinary inspection is required.~~

2. The state veterinarian may deny an import permit if the state veterinarian has information that an animal:

   a. Has not met the disease testing, vaccination, and identification requirements sets forth in North Dakota Century Code title 36 or this title, or as otherwise required by the state veterinarian;

   b. Has not met or satisfied any preentry quarantine conditions imposed by law;

c. Is or may be infected with any contagious or infectious disease;

d. Has been exposed or may have been exposed to any contagious or infectious disease;

e. Is or may originate from an area or premises under quarantine or other form of official or regulatory action relating to contagious or infectious disease; or

f. May be a threat to the health and well-being of the human or animal population of the state, or both.

History: Amended effective September 1, 1988; May 1, 2003.
General Authority: NDCC 36-01-08, 36-21.1-12
Law Implemented: NDCC 36-01-08, 36-01-12, 36-21.1-12

48-02-01-04. Bison.

1. **Tuberculosis.** A negative tuberculosis test is required on all bison except nursing calves accompanying negative-tested dams. Bison originating from tuberculosis-free states or areas that do not require North Dakota origin bison to be tested prior to entry are exempt from the tuberculosis test requirement.

2. **Brucellosis.** ~~Tests for brucellosis must be conducted by a state or federal laboratory or by a veterinarian approved in the state of origin. "Brucellosis test" means an approved blood test conducted and confirmed in an approved state or federal laboratory. A negative preentry test within thirty days will be required on test eligible bison females originating in free or class A states; those test eligible bison females originating from a class B state will require a negative preentry test within thirty days and be placed under quarantine and complete a negative ninety to one-hundred-eighty-day postentry test.~~ Test-eligible bison must have a negative brucellosis test within thirty days prior to entry into North Dakota. Bison originating from brucellosis-free states or areas that do not require North Dakota bison to be tested prior to entry are exempt from the brucellosis test requirement. Test-eligible bison are all bison over eighteen months of age except steers, spayed heifers, and official calfhood vaccinates for brucellosis under twenty-four months of age.

3. **Permits.** Permits shall be required on all bison.

4. **Dipping.** Dipping in a solution approved by the board shall be required on all bison originating from states where scabies permits are required. Two dippings, ten to fourteen days apart, may be required on bison originating from states determined by the board to have a large number of infested herds. In lieu of dipping, treatment with an approved avermectin administered by a licensed accredited

veterinarian in accordance with the United States department of agriculture, guidelines for veterinary services, found in 9 CFR part 73, is acceptable.

History: Amended effective September 1, 1988; January 1, 1994; October 1, 1998; May 1, 2003.
General Authority: NDCC 36-01-08, 36-01-12
Law Implemented: NDCC 36-01-08, 36-01-12, 36-14-04.1

48-02-01-05. Sheep.

1. For all sheep imported into North Dakota, all of the following are required:

   a. A certificate of veterinary inspection, except as otherwise provided by North Dakota Century Code sections 36-14-04.1 and 36-14-10 and North Dakota Administrative Code section 48-02-01-01.

   b. An import permit from the board.

   c. Sheep must be free of any visible signs of infectious foot rot and must originate from flocks that have been inspected and are free from any visible signs of infectious foot rot. The certificate of veterinary inspection must specifically state that all of the sheep are free of any visible signs of infectious foot rot. Special permission may be given by the state veterinarian to import registered breeding sheep without meeting the requirements of this subsection. Registered breeding sheep imported by special permission must be held under quarantine and isolated from other sheep for a minimum of thirty days, upon entry into North Dakota.

   d. ~~The~~ Unless the sheep have a QR or RR genotype at codon 171 as verified by two blood tests conducted at least two weeks apart and drawn under the supervision of an accredited veterinarian or state or federal veterinarian, certificate of veterinary inspection must contain a written statement, signed by the owner of the sheep, stating that:

      "To the best of my knowledge, the sheep listed on this certificate originate from a flock that has not been diagnosed as a scrapie-infected, source, trace, or exposed flock in the past five years. (This statement shall be signed by the owner.)"

2. All breeding rams imported into North Dakota must comply with all of the following requirements:

   a. Breeding rams six months of age or over must have had a negative test for brucella ovis, or the flock of origin must have a negative

brucella ovis status. To qualify a flock as a negative brucella ovis status flock, two negative tests for brucella ovis must have been administered, forty-five to sixty days apart, during the same year, to all rams one year of age or older, and thereafter a yearly negative test must have been administered to all rams in the flock one year of age or older. The certificate of veterinary inspection must include specific negative test information concerning brucella ovis.

b. Rams must be individually identified with registration ear tag or tattoo, or other identification approved by the state veterinarian.

3. All rams sold for breeding purposes in North Dakota must comply with all of the following requirements:

a. Breeding rams six months of age or over must have had a negative test for brucella ovis, or the flock of origin must have a negative brucella ovis status. To qualify a flock as a negative brucella ovis status flock, two negative tests for brucella ovis must have been administered, forty-five to sixty days apart, during the same year, to all rams one year of age or older, and thereafter a yearly negative test must have been administered to all rams in the flock one year of age or older.

b. Rams testing positive to an official brucella ovis test must be isolated, branded with a B brand on the left jaw, and sold for slaughter only, or they must be neutered before leaving the premises.

c. Rams must be individually identified by registration ear tag or tattoo, or other identification approved by the state veterinarian.

4. All tests for brucella ovis administered pursuant to this section must be tests officially recognized or otherwise approved by the state veterinarian.

History: Amended effective July 1, 1988; September 1, 1988; October 1, 1999; May 1, 2003.
General Authority: NDCC 36-01-08, 36-01-12
Law Implemented: NDCC 36-01-08, 36-01-12, 36-14-04.1, ~~36-14-10~~

48-02-01-08. Dogs and cats. ~~Dogs and cats must have a~~

1. No person may import any dog or cat over three months of age without certification of ~~no known exposure to rabies within one hundred days prior to importation. If over three months of age, dogs and cats must be vaccinated for rabies. The state game and fish department requires hunting dogs to have been vaccinated at least thirty days prior to import date~~ a current rabies vaccination. When an area is quarantined for rabies, a certifying statement is required from an accredited veterinarian

that the dog or cat has not been exposed to rabies ~~and has a current rabies vaccination is required. No dogs or cats~~. No person may import any dog or cat less than three months of age ~~will be accepted~~ from an area under quarantine for rabies.

A certificate of veterinary inspection is not required unless:

a. The animal originates from an area quarantined for rabies;

b. The animal originates from a foreign country other than Canada;

c. The animal is to remain in the state for thirty days or more;

d. A resident travels with an animal to another state or province and does not return within thirty days; or

e. The state veterinarian determines that it is necessary based on disease information for a time period not to exceed the term of the threat.

2. If a certificate of veterinary inspection is required as stated above, the certificate of veterinary inspection shall be obtained prior to entry of the animal into the state.

3. If the state veterinarian determines that it is necessary to require certificates of veterinary inspection, the state veterinarian shall publicize the requirement for the certificate of veterinary inspection.

4. It is not a violation of this section to bring a dog or cat from a bordering state for the purpose of obtaining any vaccination or other health care from a licensed veterinarian or to an animal shelter for care and adoption.

History: Amended effective September 1, 1988; October 1, 1998; May 1, 2003.
General Authority: NDCC 36-01-08, 36-01-12
Law Implemented: NDCC 36-01-08, 36-01-12, 36-14-04.1

48-02-01-09. Horses. All equine species require negative tests for equine infectious anemia within twelve months prior to date of importation, unless originating from states exempted from test requirements by the state veterinarian. North Dakota horses testing positive to equine infectious anemia must be positively and individually identified by permanent brand.

A certificate of veterinary inspection is not required for horses entering the state for less than seven days if an official copy of a negative equine infectious anemia test within the last twelve months accompanies the horse unless the state veterinarian determines that it is necessary based on disease information for a time period not to exceed the term of the threat. If the state veterinarian determines that

it is necessary to require certificates of veterinary inspection, the state veterinarian shall publicize the requirement for the certificate of veterinary inspection.

History: Amended effective June 1, 1983; September 1, 1988; May 1, 2003.
General Authority: NDCC 36-01-08
Law Implemented: NDCC 36-01-08

CHAPTER 48-02-02

48-02-02-01. Livestock exhibition and import for exhibition.

1. ~~For all~~ All livestock imported for exhibition purposes~~;~~ must be accompanied by a certificate of veterinary inspection ~~is required~~ and the owner of such livestock, or the owner's agent, must comply with the import permit requirements under this article.

2. Equine species require a negative test for equine infectious anemia within twelve months prior to date of importation, unless originating from a state exempted from the test requirement by the North Dakota state veterinarian.

3. For all cattle imported for exhibition purposes, a negative brucellosis test is required within thirty days prior to date of entry unless the cattle are official brucellosis vaccinates originating from certified free herds or areas. Female cattle, not vaccinated for brucellosis, over one year of age, may be imported for exhibition purposes only. A permit is required for all female cattle over one year of age and for all cattle originating from any state where scabies may be introduced, as determined by the board.

4. Sheep imported for exhibition purposes must meet the same requirements as sheep imports for other purposes.

5. All swine imported into North Dakota being used for exhibition purposes must meet the same requirements as swine imports for other purposes.

6. All animals leaving the state for exhibition or competition with a valid certificate of veterinary inspection may return to the state with the same certificate of veterinary inspection if the animal has not been out of the state for more than thirty days.

History: Amended effective September 1, 1988; May 1, 2003.
General Authority: NDCC 36-01-08, 36-01-12
Law Implemented: NDCC 36-01-08, 36-01-12, 36-14-04.1, 36-21.1-12

CHAPTER 48-12-01

48-12-01-02. Definitions. For purposes of this chapter:

1. "Board" means the North Dakota board of animal health.

2. "Domestic animal" means dog, cat, horse, bovine animal, sheep, goat, bison, llama, alpaca, or swine.

3. "Herd" means all animals commingled with other animals of the same species owned by the same person, which are confined to specific premises.

4. "Hybrid" means an animal produced by crossing species or subspecies.

5. "Import permit" or "importation permit" means a premovement authorization for entry into North Dakota obtained from the office of the state veterinarian.

6. "License" means a document obtained from the board for the raising or propagation of a species in North Dakota.

~~6.~~ 7. "Nontraditional livestock" means any wildlife held in a cage, fence, enclosure, or other manmade means of confinement that limits its movement within definite boundaries, or an animal that is physically altered to limit movement and facilitate capture.

Category 1: Those animals that are similar to but have not been included as domestic species, including turkeys, geese, ducks (morphologically distinguishable from wild turkeys, geese, ducks), pigeons, and mules or donkeys. (These animals are subject to the rules of domestic animals.)

Category 2: Those species that have been domesticated, including ostrich, emu, chinchilla, guinea fowl, ferret, ranch foxes, ranch mink, peafowl, all pheasants not in category 3, quail, chukar, and Russian lynx. Category 2 species imported must meet the health requirements as set forth in this chapter.

Category 3: Those species that are indistinguishable from wild, indigenous species or present a health risk to wild and domestic species, or both, including elk, deer (except those listed under subdivisions a and b of subsection 3 of section 48-12-01-03), reindeer, bighorn sheep, fallow deer, ring-necked pheasant, Bohemian pheasant, sichuan pheasant, Canadian lynx, bobcat, and raptor.

Category 4: Those species that are considered inherently or environmentally dangerous, including bears, wolves, wolf hybrids, primates, lions, tigers, and cats (not listed previously).

Category 5: Those species that are not categorized in categories 1 through 4 require a special license, the requirements of which will be established by the board.

~~7. "Permit" means a document obtained from the board for the importation of animals into North Dakota.~~

8. "Person" means any individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity.

9. "Possess" means to own, control, restrain, transport, or keep in captivity.

10. "Zoo" means an organization with a class C exhibitor's permit, which follows United States department of agriculture (USDA) regulations and are inspected by USDA/APHIS.

History: Effective March 1, 1994; amended effective October 1, 1998; May 1, 2003.
General Authority: NDCC 36-01-08
Law Implemented: NDCC 36-01-08, 36-01-12

48-12-01-02.1. Importation permit required - Denial - Exemptions.

1. Except as provided in this section, no person may import any nontraditional livestock without first obtaining an import permit from the office of the state veterinarian. The import permit number must be written on the certificate of veterinary inspection, unless the nontraditional livestock are being imported without a certificate of veterinary inspection for immediate slaughter pursuant to North Dakota Century Code section 36-14-10. Import permits expire thirty days after issuance and are not transferable. Upon a determination that the import permit applicant or permittee is or has been in violation of the requirements of the subject permit or that the applicant has provided inaccurate information with respect to the permit request, the state veterinarian may deny permits issued pursuant to these rules. Import permits may be obtained from the office of the state veterinarian by calling the telephone numbers listed in section 48-01-01-01.

2. The state veterinarian may deny an import permit if the state veterinarian has information that an animal:

   a. Has not met the disease testing, vaccination, and identification requirements set forth in North Dakota Century Code title 36 or this title, or as otherwise required by the state veterinarian;

b. Has not met or satisfied any preentry quarantine conditions imposed by law;

c. Is or may be infected with any contagious or infectious disease;

d. Has been exposed or may have been exposed to any contagious or infectious disease;

e. Is or may originate from an area or premises under quarantine or other form of official or regulatory action relating to contagious or infectious disease; or

f. May be a threat to the health and well-being of the human or animal population of the state, or both.

3. Unless the state veterinarian determines it is necessary based on disease incidence information, the following are exempt from the importation permit and certificate of veterinary inspection requirement:

a. Arachnids;

b. Amphibians;

c. Invertebrates;

d. Reptiles;

e. Tropical freshwater and saltwater fish;

f. Pet birds of the psittacidae and fringillidae families;

g. Ferrets;

h. Gerbils;

i. Guinea pigs;

j. Hamsters;

k. Mice;

l. Rats;

m. Rabbits;

n. Sugar gliders; and

o. Chinchillas.

The state veterinarian shall publicize the requirement for the certificate of veterinary inspection or importation permit, or both, if the certificate of veterinary inspection or importation permit, or both, should become necessary.

History: Effective May 1, 2003.
General Authority: NDCC 36-01-08, 36-21.1-12
Law Implemented: NDCC 36-01-08, 36-01-12, 36-21.1-12

CHAPTER 48-14-02

48-14-02-01. Importation requirements. Farmed elk may be imported into North Dakota only after the owner of the farmed elk:

1. Obtains an importation permit from the state veterinarian's office;

2. Submits to the state veterinarian's office proof of a physical examination by an accredited veterinarian accompanied by an approved certificate of veterinary inspection. The certificate of veterinary inspection must include the minimum, specific disease test results, vaccinations, and health statements required by this chapter;

3. Submits to the state veterinarian's office the genetic purity test results in compliance with section 48-14-02-02. The genetic purity test results must be included with the certificate of veterinary inspection;

4. Submits to the state veterinarian's office a chronic wasting disease risk assessment form in compliance with section 48-14-02-07, unless the state veterinarian waives such requirement under subsection 2 of section 48-14-02-07; and

5. Completes and submits satisfactory proof of additional disease testing or vaccinations as may be required from the state veterinarian's office if ~~it~~ the state veterinarian has reason to believe other diseases, parasites, or other health risks are present.

History: Effective April 1, 2001; amended effective May 1, 2003.
General Authority: NDCC 36-25-02
Law Implemented: NDCC 36-14-04.1, 36-25-02

TITLE 50

STATE BOARD OF MEDICAL EXAMINERS

MARCH 2003

CHAPTER 50-02-11

50-02-11-01. Eligibility for examination. To be eligible for steps 1 and 2 of USMLE (United States medical licensing examination), the applicant must be in one of the following categories:

1. A medical student officially enrolled in, or a graduate of, a United States or Canadian medical school accredited by the liaison committee on medical education (LCME).

2. A medical student officially enrolled in, or a graduate of, a United States osteopathic medical school accredited by the American osteopathic association (AOA).

3. A medical student officially enrolled in, or a graduate of, a foreign medical school and eligible for examination by the educational commission for foreign medical graduates (ECFMG) for its certificate.

To be eligible for USMLE step 3, the applicant must (a) have obtained the MD degree or the DO degree; (b) have completed successfully both parts I and II of the national board examination or steps 1 and 2 of the USMLE or part I and step 2 or step 1 and part II or FLEX component 1; (c) if a graduate of a foreign medical school, be certified by the ECMFG or have successfully completed a fifth pathway program; and (d) have completed, or be within six months of having completed, at least one postgraduate training year in a program of graduate medical education accredited by the accreditation council for graduate medical education or the American osteopathic association or the royal college of physicians and surgeons of Canada or the college of family physicians of Canada or be enrolled in an approved postgraduate training program within the state of North Dakota.

History: Effective November 1, 1993; amended effective November 1, 1995; December 1, 1996; December 1, 2000; July 26, 2001; March 1, 2003.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-17-18

50-03-01-09.1. Physician assistant for more than one physician. A physician assistant may provide services for more than one physician in the following circumstances if each of the physicians for whom the physician assistant provides services has filed a proper contract under section 50-03-01-03:

1. In a group practice setting where one physician is designated as the primary supervising physician, the primary supervising physician will remain primarily responsible for the acts of the physician assistant even when the physician assistant is acting under the immediate supervision of another physician in the group; or

2. If two or more physicians who are not associated in practice require assistance on a part-time basis, each may contract with the physician assistant as a supervising physician provided that a physician assistant ~~is not employed in more than three practice locations~~ has one primary supervising physician who is affiliated with each of the unassociated practice arrangements.

History: Effective July 1, 1994; amended effective March 1, 2003.
General Authority: NDCC 43-17-13
Law Implemented: NDCC 43-17-02(10)

TITLE 54

BOARD OF NURSING

MAY 2003

CHAPTER 54-02-05

54-02-05-05.1. Practice requirements for license renewal. Nursing practice for purposes of relicensure must meet or exceed ~~five~~ four hundred hours within the preceding ~~five~~ four years. Nursing is defined in subsection 6 of North Dakota Century Code section 43-12.1-02. Hours practiced in another regulated profession cannot be used for nursing practice hours.

History: Effective July 1, 1987; amended effective November 1, 1990; September 1, 1994; May 1, 1996; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(9)

CHAPTER 54-02-10
RN AND LPN NURSE LICENSURE COMPACT

54-02-10-01. Findings and declaration of purpose.

1. The party states find that:

   a. The health and safety of the public are affected by the degree of compliance with and the effectiveness of enforcement activities related to state nurse licensure laws;

   b. Violations of nurse licensure and other laws regulating the practice of nursing may result in injury or harm to the public;

   c. The expanded mobility of nurses and the use of advanced communication technologies as part of our nation's healthcare delivery system require greater coordination and cooperation among states in the areas of nurse licensure and regulation;

   d. New practice modalities and technology make compliance with individual state nurse licensure laws difficult and complex; and

   e. The current system of duplicative licensure for nurses practicing in multiple states is cumbersome and redundant to both nurses and states.

2. The general purposes of this compact are to:

   a. Facilitate the states' responsibility to protect the public's health and safety;

   b. Ensure and encourage the cooperation of party states in the areas of nurse licensure and regulation;

c. Facilitate the exchange of information between party states in the areas of nurse regulation, investigation, and adverse actions;

d. Promote compliance with the laws governing the practice of nursing in each jurisdiction; and

e. Invest all party states with the authority to hold a nurse accountable for meeting all state practice laws in the state in which the patient is located at the time care is rendered through the mutual recognition of party state licenses.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-02. Definitions. As used in this compact:

1. "Adverse action" means a home or remote state action.

2. "Alternative program" means a voluntary, nondisciplinary monitoring program approved by a nurse licensing board.

3. "Compact" means the nurse licensure compact.

4. "Coordinated licensure information system" means an integrated process for collecting, storing, and sharing information on nurse licensure and enforcement activities related to nurse licensure laws, which is administered by a nonprofit organization composed of and controlled by state nurse licensing boards.

5. "Current significant investigative information" means:

   a. Investigative information that a licensing board, after a preliminary inquiry that includes notification and an opportunity for the nurse to respond if required by state law, has reason to believe is not groundless and, if proved true, would indicate more than a minor infraction; or

   b. Investigative information that indicates that the nurse represents an immediate threat to public health and safety regardless of whether the nurse has been notified and had an opportunity to respond.

6. "Home state" means the party state which is the nurse's primary state of residence.

7. "Home state action" means any administrative, civil, equitable, or criminal action permitted by the home state's laws which are imposed on a nurse by the home state's licensing board or other authority, including actions against an individual's license such as revocation,

suspension, probation, or any other action which affects a nurse's authorization to practice.

8. "Licensing board" means a party state's regulatory body responsible for issuing nurse licenses.

9. "Multistate licensure privilege" means current, official authority from a remote state permitting the practice of nursing as either a registered nurse or a licensed practical or vocational nurse in such party state. All party states have the authority, in accordance with existing state due process law, to take actions against the nurse's privilege such as revocation, suspension, probation, or any other action which affects a nurse's authorization to practice.

10. "Nurse" means a registered nurse or licensed practical or vocational nurse, as those terms are defined by each party's state practice laws.

11. "Party state" means any state that has adopted this compact.

12. "Primary state of residence" means the state of a person's declared fixed permanent and principal home for legal purposes or domicile.

13. "Public" means any individual or entity other than designated staff or representatives of party state boards or the national council of state boards of nursing, incorporated.

14. "Remote state" means a party state, other than the home state:

    a. Where the patient is located at the time nursing care is provided; or

    b. In the case of the practice of nursing not involving a patient, in such party state where the recipient of nursing practice is located.

15. "Remote state action" means:

    a. Any administrative, civil, equitable, or criminal action permitted by a remote state's laws which are imposed on a nurse by the remote state's licensing board or other authority, including actions against an individual's multistate licensure privilege to practice in the remote state; and

    b. Cease and desist and other injunctive or equitable orders issued by remote states or the licensing boards thereof.

16. "State" means a state, territory, or possession of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

17. "State practice laws" means those individual party's state laws and regulations that govern the practice of nursing, define the scope of

nursing practice, and create the methods and grounds for imposing discipline. "State practice laws" does not include the initial qualifications for licensure or requirements necessary to obtain and retain a license, except for qualifications or requirements of the home state.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-03. General provisions and jurisdiction.

1. A license to practice registered nursing issued by a home state to a resident in that state will be recognized by each party state as authorizing a multistate licensure privilege to practice as a registered nurse in such party state. A license to practice licensed practical or vocational nursing issued by a home state to a resident in that state will be recognized by each party state as authorizing a multistate licensure privilege to practice as a licensed practical or vocational nurse in such party state. In order to obtain or retain a license, an applicant must meet the home state's qualifications for licensure and license renewal as well as all other applicable state laws.

2. Party states may, in accordance with state due process laws, limit or revoke the multistate licensure privilege of any nurse to practice in their state and may take any other actions under their applicable state laws necessary to protect the health and safety of their citizens. If a party state takes such action, it shall promptly notify the administrator of the coordinated licensure information system. The administrator of the coordinated licensure information system shall promptly notify the home state of any such actions by remote states.

3. Every nurse practicing in a party state must comply with the state practice laws of the state in which the patient is located at the time care is rendered. In addition, the practice of nursing is not limited to patient care, but shall include all nursing practice as defined by the state practice laws of a party state. The practice of nursing will subject a nurse to the jurisdiction of the nurse licensing board and the courts, as well as the laws, in that party state.

4. This compact does not affect additional requirements imposed by states for advanced practice registered nursing. However, a multistate licensure privilege to practice registered nursing granted by a party state shall be recognized by other party states as a license to practice registered nursing if one is required by state law as a precondition for qualifying for advanced practice registered nurse authorization.

5. Individuals not residing in a party state shall continue to be able to apply for nurse licensure as provided for under the laws of each party state. However, the license granted to these individuals will not be recognized

as granting the privilege to practice nursing in any other party state unless explicitly agreed to by that party state.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-04. Applications for licensure in party state.

1. Upon application for a license, the licensing board in a party state shall ascertain, through the coordinated licensure information system, whether the applicant has ever held, or is the holder of, a license issued by any other state, whether there are any restrictions on the multistate licensure privilege, and whether any other adverse action by any state has been taken against the license.

2. A nurse in a party state shall hold licensure in only one party state at a time, issued by the home state.

3. A nurse who intends to change primary state of residence may apply for licensure in the new home state in advance of such change. However, new licenses will not be issued by a party state until after a nurse provides evidence of change in primary state of residence satisfactory to the new home state's licensing board.

4. When a nurse changes primary state of residence by:

   a. Moving between two party states, and obtains a license from the new home state, the license from the former home state is no longer valid;

   b. Moving from a nonparty state to a party state, and obtains a license from the new home state, the individual state license issued by the nonparty state is not affected and will remain in full force if so provided by the laws of the nonparty state; and

   c. Moving from a party state to a nonparty state, the license issued by the prior home state converts to an individual state license, valid only in the former home state, without the multistate licensure privilege to practice in other party states.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-05. Adverse actions. In addition to the general provisions described in section 54-02-10-03, the following provisions apply:

1. The licensing board of a remote state shall promptly report to the administrator of the coordinated licensure information system any remote state actions, including the factual and legal basis for such action, if known. The licensing board of a remote state shall also promptly report any significant current investigative information yet to result in a remote state action. The administrator of the coordinated licensure information system shall promptly notify the home state of any such reports.

2. The licensing board of a party state shall have the authority to complete any pending investigations for a nurse who changes primary state of residence during the course of such investigations. It shall also have the authority to take appropriate actions and shall promptly report the conclusions of such investigations to the administrator of the coordinated licensure information system. The administrator of the coordinated licensure information system shall promptly notify the new home state of any such actions.

3. A remote state may take adverse action affecting the multistate licensure privilege to practice within that party state. However, only the home state shall have the power to impose adverse action against the license issued by the home state.

4. For purposes of imposing adverse action, the licensing board of the home state shall give the same priority and effect to reported conduct received from a remote state as it would if such conduct had occurred within the home state. In so doing, it shall apply its own state laws to determine appropriate action.

5. The home state may take adverse action based on the factual findings of the remote state, so long as each state follows its own procedures for imposing such adverse action.

6. Nothing in this compact shall override a party state's decision that participation in an alternative program may be used in lieu of licensure action and that such participation shall remain nonpublic if required by the party state's laws. Party states must require nurses who enter any alternative programs to agree not to practice in any other party state during the term of the alternative program without prior authorization from such other party state.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-06. Additional authorities invested in party state nurse licensing boards. Notwithstanding any other powers, party state nurse licensing boards shall have the authority to:

1. If otherwise permitted by state law, recover from the affected nurse the costs of investigations and disposition of cases resulting from any adverse action taken against that nurse;

2. Issue subpoenas for both hearings and investigations which require the attendance and testimony of witnesses and the production of evidence. Subpoenas issued by a nurse licensing board in a party state for the attendance and testimony of witnesses, or the production of evidence, or both, from another party state, shall be enforced in the latter state by any court of competent jurisdiction, according to the practice and procedure of that court applicable to subpoenas issued in proceedings pending before it. The issuing authority shall pay any witness fees, travel expenses, mileage, and other fees required by the service statutes of the state where the witnesses or evidence, or both, are located;

3. Issue cease and desist orders to limit or revoke a nurse's authority to practice in their state; and

4. Promulgate uniform rules and regulations as provided for in subsection 3 of section 54-02-10-08.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-07. Coordinated licensure information system.

1. All party states shall participate in a cooperative effort to create a coordinated data base of all licensed registered nurses and licensed practical or vocational nurses. This system will include information on the licensure and disciplinary history of each nurse, as contributed by party states, to assist in the coordination of nurse licensure and enforcement efforts.

2. Notwithstanding any other provision of law, all party states' licensing boards shall promptly report adverse actions, actions against multistate licensure privileges, any current significant investigative information yet to result in adverse action, denials of applications, and the reasons for such denials, to the coordinated licensure information system.

3. Current significant investigative information shall be transmitted through the coordinated licensure information system only to party state licensing boards.

4. Notwithstanding any other provision of law, all party states' licensing boards contributing information to the coordinated licensure information system may designate information that may not be shared with nonparty

states or disclosed to other entities or individuals without the express permission of the contributing state.

5. Any personally identifiable information obtained by a party states' licensing board from the coordinated licensure information system may not be shared with nonparty states or disclosed to other entities or individuals, except to the extent permitted by the laws of the party state contributing the information.

6. Any information contributed to the coordinated licensure information system that is subsequently required to be expunged by the laws of the party state contributing that information shall also be expunged from the coordinated licensure information system.

7. The compact administrators, acting jointly with each other and in consultation with the administrator of the coordinated licensure information system, shall formulate necessary and proper procedures for the identification, collection, and exchange of information under this compact.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-08. Compact administration and interchange of information.

1. The head of the nurse licensing board, or that person's designee, of each party state shall be the administrator of this compact for that state.

2. The compact administrator of each party state shall furnish to the compact administrator of each other party state any information and documents, including a uniform data set of investigations, identifying information, licensure data, and disclosable alternative program participation information to facilitate the administration of this compact.

3. Compact administrators shall have the authority to develop uniform rules to facilitate and coordinate implementation of this compact. These uniform rules shall be adopted by party states, under the authority invested under subsection 4 of section 54-02-10-06.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-09. Immunity. No party state or the officers or employees or agents of a party state's nurse licensing board who acts in accordance with the provisions of this compact shall be liable on account of any act or omission in good

faith while engaged in the performance of duties under this compact. Good faith in this article shall not include willful misconduct, gross negligence, or recklessness.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-10. Implementation, withdrawal, and amendment.

1. This compact shall enter into force and become effective as to any state when it has been enacted into the laws of that state. Any party state may withdraw from this compact by enacting a statute or administrative rules, repealing the same, but no such withdrawal shall take effect until six months after the withdrawing state has given notice of the withdrawal to the executive heads of all other party states.

2. No withdrawal shall affect the validity or applicability by the licensing boards of states remaining party to the compact of any report of adverse action occurring prior to the withdrawal.

3. Nothing contained in this compact shall be construed to invalidate or prevent any nurse licensure agreement or other cooperative arrangement between a party state and a nonparty state that is made in accordance with the other provisions of this compact.

4. This compact may be amended by the party states. No amendment to this compact shall become effective and binding upon the party states unless and until it is enacted into the laws or administrative rules of all party states.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-11. Construction and severability.

1. This compact shall be liberally construed so as to effectuate the purposes thereof. The provisions of this compact shall be severable and if any phrase, clause, sentence, or provision of this compact is declared to be contrary to the constitution of any party state or of the United States or the applicability thereof to any government, agency, person, or circumstance is held invalid, the validity of the remainder of this compact and the applicability thereof to any government, agency, person, or circumstance shall not be affected thereby. If this compact shall be held contrary to the constitution of any state party thereto, the compact shall remain in full force and effect as to the remaining party states and in full force and effect as to the party state affected as to all severable matters.

2. In the event party states find a need for settling disputes arising under this compact:

   a. The party states may submit the issues in dispute to an arbitration panel which will be comprised of an individual appointed by the compact administrator in the home state; an individual appointed by the compact administrator in the remote states involved; and an individual mutually agreed upon by the compact administrators of all the party states involved in the dispute.

   b. The decision of a majority of the arbitrators shall be final and binding.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

54-02-10-12. Other compact requirements - Compact administration.

1. "Head of the nurse licensing board" as used to define the compact administrator in section 54-02-10-08 means the North Dakota board of nursing.

2. Upon the effective date of this compact, the licensing board of North Dakota will participate with other licensing boards in a compact evaluation initiative, designed to evaluate the effectiveness and operability of this compact. Such compact evaluation initiative will be conducted by the nurse licensure compact administrators. A component of the compact evaluation initiative shall include a remote state identification system through which nurses will designate those remote states in which the nurse is practicing. A nurse's practice information in such identification system will be updated upon issuance and renewal of the nurse's license. The compact evaluation initiative shall continue until the year 2008, after which time a report shall be produced for comment by the participating licensing boards and will be submitted to the North Dakota legislative assembly in the form of a nurse licensure compact evaluation report.

3. To facilitate cross-state enforcement efforts, North Dakota law provides the power to recover from the affected nurse, as authorized by North Dakota Century Code section 43-12.1-13, the assessment of costs or disbursements, or both, resulting from adverse actions taken by this state against that nurse.

4. This compact is designed to facilitate the regulation of nurses and does not relieve employers from complying with statutorily imposed obligations.

5. This compact does not supersede existing state labor laws.

6. This compact does not take effect before July 1, 2003.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-51

CHAPTER 54-04.1-01

54-04.1-01-01. Nursing education loan program. The board of nursing shall create a nursing education loan program. The program ~~must~~ may be funded by:

1. ~~Eight~~ Ten dollars of each registered nurse and licensed practical nurse biennial renewal fee or ~~four~~ five dollars of each registered nurse and licensed practical nurse annual renewal fee.

2. Principle and interest payments made toward nursing education loans that do not qualify for repayment by employment.

3. Donations and bequests from individuals wishing to further the intent of the nursing education loan program.

4. Additional funds as may from time to time be designated by the board.

History: Effective October 1, 1987; amended effective November 1, 1990; March 1, 1992; February 1, 1998; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

CHAPTER 54-04.1-02

54-04.1-02-01. Qualifications. To qualify for a nursing education loan, the applicant must:

1. ~~Demonstrate financial need satisfactory to the board;~~

~~2.~~ Have all necessary application forms completed and on file in the board office by July first of the year in which ~~they wish~~ the applicant wishes to be considered by the board for a nursing education loan. Applicants for nurse refresher course nursing education loans will be considered at any board meeting; and

~~3.~~ 2. Demonstrate one of the following:

   a. Be accepted into and enrolled in a North Dakota board-approved or recognized undergraduate nursing education program for practical nurses or registered nurses;

   b. Have a current North Dakota license and have been accepted into ~~or be~~ and enrolled in an educational program that is acceptable to the board; or

   c. Be a resident of North Dakota for refresher courses and accepted into a refresher course that meets board requirements.

History: Effective October 1, 1987; amended effective October 1, 1989; March 1, 1992; November 1, 1996; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

CHAPTER 54-04.1-03

54-04.1-03-01. Amount of loans. To the extent funds are available, educational loans will be made in the following amounts:

1. Students in ~~a~~ an associate degree licensed practical nurse program ~~who plan to complete studies for an associate degree in nursing~~ may receive a loan of no more than ~~one~~ two thousand dollars ~~for each of the two years of the nursing program~~.

2. Students in a baccalaureate registered nurse program ~~who plan to complete studies for a baccalaureate degree in nursing~~ may receive a loan of no more than ~~one~~ two thousand dollars ~~for each of the last two years of the nursing program~~.

3. Graduate nurse students may receive a loan of no more than two thousand five hundred dollars to complete studies for a master's degree in nursing. Graduate nurse students pursuing a doctorate may receive a loan of up to five thousand dollars.

4. Licensed practical nurses or registered nurses may receive a loan of no more than the cost of the course for a board-approved nurse refresher course.

History: Effective October 1, 1987; amended effective October 1, 1989; March 1, 1992; February 1, 1998; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

54-04.1-03-03. Disbursements. Disbursements of the loans will be made ~~as follows:~~ in one payment or as directed by the board.

~~1. For programs leading to initial licensure as a licensed practical nurse or a registered nurse, the total amount of the loan will be divided into equal payments for each academic term needed to complete the program, not to exceed four academic terms.~~

~~2. For licensed practical nurses who plan to complete studies for an associate degree and licensed registered nurses who plan to complete studies for a baccalaureate degree, the total amount of the loan will be divided into equal payments for each academic term needed to complete the program, not to exceed four academic terms.~~

~~3. For graduate nurse students, who plan to complete studies leading to a master's degree, the total amount of the loan will be made in one payment. For graduate nurse students who plan to complete studies leading to a doctoral degree, two equal payments will be made. The~~

~~first payment will be made upon acceptance into the doctoral program, the second payment upon achieving candidacy status.~~

History: Effective October 1, 1987; amended effective March 1, 1992; February 1,1998; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

54-04.1-03-04. Subsequent disbursements. Repealed effective May 1, 2003. ~~Subsequent disbursements of the loan, to be made beyond the initial disbursements made under the formula set out in section 54-04.1-03-03, will be made if the recipient provides the board with proof of maintaining a satisfactory grade for progression in the program as determined by the faculty of the nursing program.~~

~~**History:** Effective October 1, 1987; amended effective March 1, 1992.~~
~~**General Authority:** NDCC 43-12.1-08~~
~~**Law Implemented:** NDCC 43-12.1-08(14)~~

54-04.1-03-05. Disbursements - Where made. For practical nurse students and registered nurse students, the disbursements will be made to the school they are attending. For graduate nurse students ~~and registered nurse or licensed practical nurses attending specialty courses~~, the disbursements will be made directly to the student. A receipt of payment signed by the loan recipient will be required when the disbursement is made directly to the recipient.

History: Effective October 1, 1987; amended effective March 1, 1992; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

54-04.1-03-06. Reapplication. Reapplication may occur annually if the applicant has not received the total loan amount allowed by section 54-04.1-03-01.

History: Effective May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

CHAPTER 54-04.1-04

54-04.1-04-01. Repayment of loan by employment. The loan may be repaid by nursing employment as a licensed nurse in North Dakota after graduation. The repayment rate will be one dollar per hour of employment.

History: Effective October 1, 1987; amended effective March 1, 1992; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

CHAPTER 54-04.1-05

54-04.1-05-02. Demand for payment. Demand for payment will be made on delinquent accounts. If the account is not brought up to date within thirty days of receipt of the demand for payment, the account will be referred to the collection agency, and the board may initiate disciplinary action against the licensee for ~~unprofessional conduct~~ professional misconduct.

History: Effective October 1, 1987; amended effective March 1, 1992; May 1, 2003.
General Authority: NDCC 43-12.1-08
Law Implemented: NDCC 43-12.1-08(14)

TITLE 55

STATE BOARD OF EXAMINERS FOR NURSING HOME ADMINISTRATORS

DECEMBER 2002

CHAPTER 55-02-01

55-02-01-02. General definitions. In this article unless the subject matter or context requires otherwise:

1. "Board" means the North Dakota state board of examiners for nursing home administrators.

2. "General administrative charge of a North Dakota nursing home" means a nursing home administrator whose major responsibility is the complete operation of a nursing home.

3. "Inactive license status" means the period, beginning on or after January 1, 1993, during which a duly licensed nursing home administrator has temporarily abandoned the practice of nursing home administration in the state of North Dakota.

4. "Initial licensure" means the first time a person is licensed in North Dakota, but does not include emergency licensure or licensure by endorsement.

5. "Licensure by endorsement" means licensure pursuant to North Dakota Century Code section 43-34-12.

6. "Nursing home" means any institution or facility defined as such for licensing purposes under North Dakota state law or pursuant to the rules for nursing homes by the state department of health, whether proprietary or nonprofit, including nursing homes owned or administered by the state government or an agency or political subdivision thereof.

~~5.~~ 7. "Nursing home administrator" means a person who administers, manages, supervises, or is in general administrative charge of a North Dakota nursing home.

~~6.~~ 8. "Person" means an individual and does not include the terms firm, corporation, association, partnership, institution, public body, joint stock association, or any other group of individuals.

9. "Preceptor" means a nursing home administrator who meets the following criteria:

a. The person is licensed in good standing and has been licensed for at least one year as a North Dakota nursing home administrator.

b. The person is practicing and has practiced for at least three years as a licensed nursing home administrator in any jurisdiction.

c. The person has attended a preceptor training program recognized by the board.

History: Amended effective February 1, 1993; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-09
Law Implemented: NDCC 43-34-01, 43-34-09

55-02-01-05. Duties of board of officers.

1. The chairperson shall preside at all meetings of the board, and shall sign all official documents of the board.

2. In the absence of the chairperson, the vice chairperson shall preside at meetings, and perform all duties usually performed by the chairperson.

3. The secretary-treasurer shall keep a full and complete record of the minutes of the meetings, maintain records pertaining to licensees and registrants, ~~and~~ maintain financial records approved by the board and the fiscal authorities of the state, and make payments with the approval of the board. Any functions of the secretary-treasurer may be delegated by the board to the executive secretary.

History: Amended effective February 1, 1993; June 1, 1996; December 1, 2002.
General Authority: NDCC 43-34-07, 43-34-09
Law Implemented: NDCC 43-34-07, 43-34-09

55-02-01-06. Administration of examinations.

1. The board shall administer or contract for examinations to applicants for licensure as a nursing home administrator. ~~The scope, content, and form of any examination shall be the same for all applicants.~~

~~2. Examinations shall be held as often as deemed necessary but at least once a year, at such time and place as shall be designated by the~~

~~board. The board shall give a fifteen-day notice prior to the holding of an examination.~~

~~3.~~ 2. A record of the examination for each applicant shall be kept by the board for a period of two years.

History: Amended effective February 1, 1993; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-09

55-02-01-07. Requirements for initial licensure. A person ~~may not be permitted to take an examination for licensure as a nursing home administrator unless the person first submits evidence satisfactory to the board that the person~~ applying for initial licensure must meet the following requirements:

1. The person is at least eighteen years of age and of good moral character.

~~1.~~ 2. ~~Has~~ The person has a baccalaureate degree from an accredited college or university~~; and~~, or has an associate degree from an accredited college or university and has practiced as a licensed nursing home administrator in any jurisdiction for at least five of the last six years.

~~2.~~ 3. ~~Has~~ The person has completed a board-approved administrator-in-training program, practiced as a licensed nursing home administrator in any jurisdiction for at least two years preceding the application, or is certified by the American college of health care administrators as a nursing home administrator.

4. The person has passed or passes the required examination within one year of making an application.

History: Amended effective July 1, 1979; February 1, 1993; June 1, 1996; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-08, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-09, 43-34-12

55-02-01-08. Application for ~~examination~~ initial licensure. An applicant for ~~examination and qualification for~~ initial licensure as a nursing home administrator must make application in writing on forms provided by the board, furnish evidence satisfactory to the board that the applicant meets the licensure requirements as provided for in section 55-02-01-07, pay an application fee of one hundred dollars, and ~~pay an examination fee of twenty-five dollars plus~~ the cost charged by the national association of boards of examiners of long-term care administrators for the ~~written~~ examination. An applicant for ~~examination~~

initial licensure must submit two references from individuals engaged in business, professional, or religious work.

History: Amended effective February 1, 1993; June 1, 1996; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-05, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-05, 43-34-09

55-02-01-09. ~~Disqualification~~ Denial of initial licensure.

1. An applicant for ~~examination~~ initial licensure who has been ~~disqualified~~ denied shall be given written notification by the board of the ~~applicant's disqualification and~~ denial, the reasons ~~therefore~~ for denial, and of the applicant's right to a hearing.

2. An applicant for ~~examination~~ initial licensure who has been ~~disqualified~~ denied may petition the board in writing within thirty days of notification of ~~disqualification~~ the denial for a hearing and a review of the applicant's application in accordance with North Dakota Century Code chapter 28-32.

~~3. An applicant for examination who has been disqualified may submit a new application for qualification for examination. The applicant shall be required to meet the requirements for licensure in force at the time of such reapplication.~~

History: Amended effective February 1, 1993; December 1, 2002.
General Authority: NDCC ~~43-34-03~~ 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-09

55-02-01-10. Examination.

~~1.~~ ~~Every applicant~~ Each person applying for licensure as a nursing home administrator, except ~~an individual~~ a person applying for emergency licensure ~~through endorsement~~ or licensure by endorsement, is required to pass ~~a written national~~ an examination.

~~2. The board shall use as a basis for an oral examination a written outline of the subject matter that may include:~~

~~a. Applicable standards of environmental health and safety;~~

~~b. Local health and safety regulations;~~

~~c. General administration;~~

~~d. Psychology of patient care;~~

~~e. Principles of medical care;~~

~~f. Personal and social care;~~

~~g. Therapeutic and supportive care and services in long-term care;~~

~~h. Departmental organization and management; and~~

~~i. Community interrelationships.~~

~~3.~~ ~~The board shall use the test~~ provided by the national association of boards of examiners of long-term care administrators ~~for the written examination~~.

History: Amended effective February 1, 1993; June 1, 1996; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-09

55-02-01-11. Grading examinations.

~~1. Grading must be pass or fail for an oral examination.~~

~~2. The national scale score shall be used to determine a passing point for the written examination.~~ A passing score for a written examination shall be the passing score established by the national association of boards of examiners of long-term care administrators.

History: Amended effective July 1, 1981; June 1, 1983; February 1, 1993; June 1, 1996; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-09

55-02-01-12. Continuing education.

1. Twenty hours of continuing education must be obtained each calendar year. ~~A record of continuing education must be submitted with the application for renewal of license.~~ except during the first year of licensure, a licensee must obtain:

   a. Twenty hours of continuing education if licensed before April first;

   b. Fifteen hours of continuing education if licensed before July first; or

   c. Ten hours of continuing education if licensed before October first.

2. Continuing education hours must be obtained from providers approved by the board.

3. Documentation of continuing education must be submitted with a renewal application.

History: Amended effective February 1, 1993; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-04, 43-34-09
Law Implemented: NDCC ~~43-34-03~~ 43-34-09, 43-34-10

55-02-01-15. ~~Licenses~~ Licensure by endorsement.

~~1. An applicant for licensure as a nursing home administrator who has successfully complied with the requirements of North Dakota Century Code chapter 43-34 and this chapter and has passed the examinations provided in section 55-02-01-10 shall be issued a license certifying that the applicant has met the requirements of the laws and rules entitling the applicant to serve, act, practice, and otherwise hold oneself out as a duly licensed nursing home administrator.~~

~~2. The board may, upon application, issue a provisional license to any person who:~~

~~a. Meets the requirements for licensure set forth in section 55-02-01-07;~~

~~b. Has a bona fide offered position as a nursing home administrator; and~~

~~c. Has never previously held a provisional license in North Dakota.~~

~~3. The provisional license is valid until the results of the next scheduled written examination are received by the board.~~

~~4.~~ Upon application, the board may issue a license ~~through~~ by endorsement to any person who:

~~a. Has received a passing grade on a national exam recognized by the national association of boards of examiners of long-term care administrators;~~

~~b. Pays an application fee of one hundred dollars;~~

~~c. Holds a valid license from the transferring state; and~~

~~d. Satisfies the licensure requirements under section 55-02-01-07, has been employed as a licensed nursing home administrator for at least thirty-six months of the forty-eight months immediately preceding the application, or is certified by the American college of health care administrators.~~

1. Pays an application fee of one hundred dollars.

2. Holds a current license in good standing from another jurisdiction that imposes requirements for obtaining a license which are at least as stringent as the requirements imposed in this state.

History: Amended effective February 1, 1993; June 1, 1996; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-09
Law Implemented: NDCC ~~43-34-04~~ 43-34-03, 43-34-05, 43-34-09, 43-34-12

55-02-01-15.1. Emergency license. Upon application, the board may issue an emergency license to any person who:

1. Pays an application fee of one hundred dollars.

2. Meets the requirements of subsection 1 of section 55-02-01-07.

3. Will be supervised by a preceptor at the expense of the nursing home. Supervision requires communication between the preceptor and the licensee at least twice in each week and at least one visit in each month by the preceptor to the nursing home where the licensee is employed. The preceptor shall make monthly written reports to the board.

4. Meets any other requirements that the board finds necessary.

History: Effective December 1, 2002.
General Authority: NDCC 43-34-04, 43-34-05, 43-34-09
Law Implemented: NDCC 43-34-05, 43-34-09, 43-34-11

55-02-01-16. Registration and renewal of licenses.

1. Any person who holds a license issued by the board shall be registered with the board. The license expires on the thirty-first day of December in the year of its issuance and is renewable annually upon payment of the license fee. The board shall transmit renewal forms to all licensees whose licenses expire on December thirty-first.

2. The licensee shall pay an annual ~~license~~ renewal fee of one hundred twenty-five dollars.

3. ~~Upon receipt of the renewal form, documentation of the continuing education hours required in section 55-02-01-12, and the license fee, the board shall issue a license.~~ An applicant for renewal shall provide documentation of completion of the continuing education required by section 55-02-01-12.

4. The board shall maintain a register of all licensed nursing home administrators. The board shall maintain a complete file of such pertinent information as may be deemed necessary.

5. A licensee who does not meet the requirement for renewal by December thirty-first may renew the license by meeting the requirements and paying a late renewal fee in the amount of twenty-five dollars per month for each month following December thirty-first. If the requirements for renewal are not met by June thirtieth of the year following the renewal year, the license expires.

History: Amended effective February 1, 1993; June 1, 1996; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-04, 43-34-05, 43-34-09~~, 43-34-10~~
Law Implemented: NDCC 43-34-05, 43-34-09, 43-34-10

55-02-01-17. ~~Refusal~~ Denial, suspension, and revocation of licenses. The board, after notice and opportunity for hearing, may deny an application for license, suspend, or revoke~~, or refuse to issue~~ a license for a nursing home administrator, or may reprimand or otherwise discipline a licensee, ~~or provisional licensee, after due notice and an opportunity to be heard at a formal hearing, upon substantial evidence that~~ if the licensee~~, provisional licensee,~~ or applicant for license:

1. Has violated any of the provisions of the law pertaining to the licensing of nursing home administrators or the rules and regulations of the board pertaining thereto;

2. Has ~~willfully or repeatedly~~ violated any of the provisions of the law, rules, or regulations of the licensing authority having jurisdiction ~~of~~ over the operation and licensing of nursing homes;

3. Has practiced fraud, deceit, or misrepresentation or provided misleading omission or material misstatement of fact in securing ~~or~~, procuring, renewing, or maintaining a nursing home administrator license;

4. Has ~~practiced fraud, deceit, or misrepresentation~~ engaged in fraudulent, deceptive, or dishonest conduct in the licensee's capacity as a nursing home administrator;

5. Has committed acts of professional misconduct or professional negligence in a nursing home;

6. Has practiced without a license;

7. Has ~~wrongfully~~ transferred or surrendered possession~~, either temporarily or permanently,~~ of the licensee's license to any other person;

8. Has ~~been guilty of fraudulent, misleading, or deceptive~~ engaged in fraudulent, misleading, or deceptive advertising with respect to the facility;

9. Has ~~falsely~~ impersonated another licensee ~~of a like or different name~~;

10. Has ~~willfully~~ failed to exercise true regard for the safety, health, and life of the resident;

11. Has ~~willfully~~ permitted unauthorized or illegal disclosure of information relating to a resident or the resident's records; ~~or~~

12. Has ~~willfully~~ discriminated in respect to residents~~, employees,~~ or staff ~~on account of~~ with regard to race, religion, color, age, sex, creed, marital status, disability, status with regard to public assistance, or national origin~~.~~;

13. Has been convicted of an offense having a direct bearing on the applicant or licensee's ability to serve the public as a nursing home administrator or, following conviction of any offense, has been determined by the board to be insufficiently rehabilitated under North Dakota Century Code section 12.1-33-02.1;

14. Has engaged in sexual harassment, made sexual advances toward, or engaged in sexual contact with any resident, or engaged in sexual harassment of any employee, student, trainee, volunteer, consultant, or visitor to the facility in which the licensee practices;

15. Has used the licensee's professional status, title, position, or relationship as a nursing home administrator or licensee to coerce, improperly influence, or obtain money, property, or services from a resident, resident's family member, visitor, employee, or any person served by or doing business with the nursing facility that the licensee administers or is employed by;

16. Has made a false statement or provided false or misleading information to the board, failed to submit reports as required by the board, failed to cooperate with an investigation of the board, or violated an order of the board;

17. Has failed to report a reprimand, restriction, limitation, condition, revocation, suspension, surrender, or other disciplinary action against the person's license as a nursing home administrator in another jurisdiction, has failed to report the existence of a complaint or other charges against the person's nursing home administrator license in another jurisdiction, or has been denied a license as a nursing home administrator by any other jurisdiction;

18. Has abused or is dependent on alcohol, legend drugs, or controlled substances, and the abuse or dependency affects the performance of the licensee's duties;

19. Has forged prescriptions or made drugs available to self, friends, or family members; or

20. Has failed to complete continuing education requirements.

History: Amended effective February 1, 1993; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-03.1, 43-34-09, 43-34-10, 43-34-11, 43-34-12

55-02-01-18. ~~Complaints and administrative hearing~~ Complaint procedures.

1. ~~Any person, public officer, association, or the board, may register a complaint against a licensee. The complaint must be submitted in writing to the board.~~ Upon filing of a written and signed complaint alleging a licensee engaged in conduct identified as grounds for disciplinary action under section 55-02-01-17, the board shall notify the licensee of the complaint and require a written response from the licensee.

2. ~~The board shall conduct an investigation to determine whether an administrative hearing on the complaint is necessary.~~

3. ~~If the board decides that the complaint shall be heard, the proceedings shall be in accordance with North Dakota Century Code chapter 28-32.~~ The board shall determine if there is a reasonable basis to believe the licensee engaged in conduct identified as grounds for disciplinary action under section 55-02-01-17. If the board determines there is not a reasonable basis to believe, the board will notify the complainant and the licensee. If the board determines there is a reasonable basis to believe, the board will proceed with a disciplinary action in accordance with North Dakota Century Code chapter 28-32.

~~4. a. Upon the conclusion of the hearing, the board may revoke the license, suspend the license for a fixed period, reprimand the licensee, take other disciplinary action, or dismiss the charges.~~

~~b. An order or suspension made by the board may contain such provisions as to reinstatement of the license as the board shall direct.~~

3.c. ~~The board, upon good cause, may direct a rehearing in accordance with North Dakota Century Code section 28-32-14. Any appeal shall be~~

~~taken in the manner provided in North Dakota Century Code chapter 28-32.~~ The board, at any time, may offer or accept a proposal for informal resolution of the complaint or disciplinary action.

History: Amended effective February 1, 1993; December 1, 1998; December 1, 2002.
General Authority: NDCC ~~28-32-05~~ 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-03.1, 43-34-04, 43-34-09, 43-34-10, 43-34-11, 43-34-12

55-02-01-21. Inactive license status. A nursing home administrator whose license has not expired or been revoked or suspended may request inactive license status for no more than five consecutive years. While in inactive license status, the administrator must submit a renewal form and a license fee annually but the continuing education requirement as set forth in section 55-02-01-12 need not be met. A license may not be issued during the inactive license status period. A nursing home administrator must obtain twenty hours of continuing education hours prior to reactivating his or her license. ~~A nursing home administrator who chooses inactive license status for a period in excess of five consecutive years must pass an oral examination prior to reactivating a license.~~

History: Amended effective February 1, 1993; June 1, 1996; December 1, 1998; December 1, 2002.
General Authority: NDCC 43-34-03, 43-34-04, 43-34-09
Law Implemented: NDCC 43-34-03, 43-34-05, 43-34-09, 43-34-10

55-02-01-24. Applicability - Legal effect - Severability. Repealed effective December 1, 2002.

~~1. This chapter shall be supplemental to the law providing for the licensing of nursing home administrators and pursuant to North Dakota Century Code section 28-32-03 shall have the force and effect of law.~~

~~2. Every rule, regulation, order, and direction adopted by the board shall state the date on which it takes effect and a copy thereof signed by the chairperson of the board and the secretary-treasurer of the board shall be filed as a public record in the office of the board and in accordance with requirements in North Dakota Century Code chapter 28-32.~~

~~3. This chapter is intended to be consistent with the applicable federal and state law. If any provision of this chapter conflicts with existing or future requirements of the United States government with respect to licensing of nursing home administrators, the federal requirements must prevail.~~

~~4. In the event that any provision of this chapter is declared unconstitutional or invalid, or the application thereof to any person or circumstance is held invalid, the applicability of the provision to other persons and circumstances and the constitutionality or validity of every other provision of this chapter shall not be affected thereby.~~

~~5. This chapter shall not affect pending actions or proceedings, civil or criminal, but the same may be prosecuted or defended in the same manner and with the same effect as though this chapter has not been promulgated.~~

~~6. The board shall furnish a copy of this chapter to all applicants and licensees.~~

~~7. Amendments to this chapter may be made only by a majority vote of all members of the board.~~

History: ~~Amended effective June 1, 1996; December 1, 1998.~~
General Authority: ~~NDCC 28-32-03~~
Law Implemented: ~~NDCC 43-34-09~~

TITLE 60

PESTICIDE CONTROL BOARD

MARCH 2003

CHAPTER 60-01-01

60-01-01-01. Organization and purpose of pesticide control board.

1. **History.** The 1975 legislative assembly created the pesticide control board by legislation codified as North Dakota Century Code chapter 4-35. The purpose of the legislation is to regulate, in the public interest, the distribution, storage, transportation, disposal, and use and application of pesticides to control pests.

2. **Board membership.** The pesticide control board consists of the agriculture commissioner, who is chairman of the board; the director of the North Dakota state university extension service; and the director of the agricultural experiment station at North Dakota state university of agriculture and applied science.

3. **Enforcement responsibility.** The agriculture commissioner is responsible for the enforcement of North Dakota Century Code chapter 4-35.

4. **Inquiries.** General inquiries regarding the pesticide control board may be addressed to:

   Agriculture Commissioner, Chairman
   Pesticide Control Board
   North Dakota Department of Agriculture
   600 East Boulevard
   State Capitol, 6th Floor
   Bismarck, North Dakota 58505-0020
   (701)328-2231; e-mail *ndda@state.nd.us*

History: Amended effective January 1, 1992; March 1, 2003.
General Authority: NDCC 28-32-02.1
Law Implemented: NDCC 28-32-02.1

CHAPTER 60-03-01

60-03-01-02. Definitions. As used in this chapter, the following words shall have the meaning given to them below, unless otherwise made inappropriate by use and context. Words not defined in this section shall have the meaning given to them in North Dakota Century Code chapter 4-35.

1. "Act" means the North Dakota Pesticide Act.

2. "Board" means the North Dakota pesticide control board created pursuant to North Dakota Century Code section 4-35-02.

~~2.~~ 3. "Broadcast" means any intentional application of a pesticide over an area, such as a lawn, field, room, crawl space, or other such surface.

4. "Bulk pesticide" means any volume of pesticide ~~which~~ that is intended to be repackaged, can be accurately metered, and ~~which is~~ can be transported or held in an individual container ~~capable of holding, in undivided quantities, fifty-five United States gallons [208.2 liters] or greater, or two hundred pounds [90.72 kilograms] net dry weight~~.

~~3.~~ 5. "Bulk pesticide ~~storage~~ facility" means any area, location, tract of land, building, structure, or premises ~~constructed~~ used for the handling or storage of bulk pesticides.

~~4.~~ 6. "Certification" means certification of dealers, commercial applicators, and private applicators provided for by North Dakota Century Code sections 4-35-09, 4-35-12, and 4-35-14.

~~5.~~ 7. "Commissioner" means the North Dakota ~~commissioner of~~ agriculture commissioner.

~~6.~~ 8. "Compensation" means monetary payment for a specific service.

~~7. "Custom applicator" means any person who uses or supervises the use of a general use pesticide for compensation upon the land of another person.~~

~~8.~~ 9. "Custom blend" means any diluted mixture of pesticide prepared by a dealer to the specifications of the end-user and not held in inventory.

~~9.~~ 10. "End-use labeling" means the ~~label application recommendations for a pesticide~~ written, printed, or graphic matter on, or attached to or accompanying the pesticide or device or any of its containers or wrappers.

~~10.~~ 11. "End-user" means the person who applies the pesticide.

~~11.~~ 12. "FIFRA" means Federal Insecticide, Fungicide, and Rodenticide Act of 1947.

13. "General use pesticide" means any pesticide formulation which is not classified for restricted use by the board.

~~12.~~ 14. "Handling" means the mixing, loading, application, repackaging, storage, transportation, distribution, sale, purchase, or disposal of pesticides.

15. "~~Mix~~ Mixture" means any diluted ~~mixture~~ combination of pesticide with fertilizer, seed, or other medium.

~~13. "Pesticide applicator" means any person who applies a pesticide.~~

~~14.~~ 16. "Mobile container" means a container used to transport pesticides.

17. "Operational area" means a permanent containment area where pesticides are transferred, loaded, unloaded, mixed, repackaged, or refilled; where pesticides are cleaned or rinsed from containers; or application, handling, storage, or transportation equipment.

18. "Permanent containment area" means:

a. An aboveground pad or dike constructed of impervious material, such as sealed concrete, stainless steel, or other material as approved by the department of agriculture;

b. Bermed, curbed, sloped, or otherwise designed to contain spills, leaks, releases, or other discharges that are generated during the handling of pesticides or pesticide-containing materials;

c. Does not have a drain which exits the containment area; and

d. All seams and cracks must be sealed to prevent leakage.

19. "Pesticide-containing material" means:

a. Any container of a pesticide product that has not been triple-rinsed or the equivalent of triple-rinsed;

b. Any rinsate that is derived from a pesticide container, pesticide application equipment, or equipment washing;

c. Any material that is used to collect or contain excess or spilled pesticide or rinsate;

d. Any mixture of pesticide and diluent such as wash water, rinse water, or rainwater; or

e. Material that is generated as a result of contact with or utilization of a pesticide in an application, containment, recovery, reuse, or treatment system. The term does not include personal protective equipment that contains pesticide residue.

20. "Pesticide-producing establishment" means any site where a pesticide is manufactured, packaged, repackaged, prepared, processed, labeled, relabeled, or held for distribution.

21. "Repackaging" means the transfer of a pesticide in ~~bulk quantities and in~~ an unaltered state from a container into a designated or dedicated refillable container.

22. "Rinsate" means a dilute mixture of pesticide obtained by rinsing pesticide containers or from rinsing the inside and outside of spray equipment.

23. "Spill kit" means a portable kit or other equipment that is designed to recover, minimize, contain, or absorb spills, leaks, releases, or other discharges of pesticides.

24. "Use of a pesticide" means the loading, mixing, applying, storing, transporting, distribution, and disposing of a pesticide.

25. "Use of a pesticide in a manner inconsistent with its labeling" means to use any pesticide in a manner that is not permitted by the label, except that the term does not apply to any of the following:

a. Applying a pesticide at any dosage, concentration, or frequency that is less than that specified on the label, unless the label specifically prohibits deviation from the specified dosage, concentration, or frequency.

b. Applying a pesticide against any target pest that is not specified on the label if the application is to the crop, animal, or site that is specified on the label.

c. Employing any method of application that is not prohibited by the label unless the label specifically states that the product may be applied only by the methods specified on the labeling.

d. Mixing a pesticide or pesticides with a fertilizer when the label does not prohibit such mixture.

e. Any use of a pesticide that is in compliance with section 5, 18, or 24 of the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 [Pub. L. 104-170; Stat. 7 U.S.C. 136 et seq.].

History: Amended effective April 15, 1985; October 1, 1990; July 1,1992; March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06

60-03-01-05. ~~Certification - Commercial applicators, dealers, private applicators~~ Categories of certification. Applicators may apply for certification in one or more of the following categories:

1. ~~**Categories of certification.**~~

~~a.~~ **Agricultural pest control (plant and animal).** This category ~~includes commercial applicators using restricted use pesticides in production~~ authorizes the application or sale of pesticides intended for agricultural ~~crops including cereal grain, feed grains, soybeans, forages, large and small seeded legumes, small fruits, tree fruits, nuts, and vegetables, as well as application to~~ crop land, grasslands, and noncrop lands. This also includes the use of ~~restricted use~~ pesticides on animals~~, beef cattle, dairy cattle, swine, sheep, horses, goats, poultry, and other livestock,~~ and ~~also to places on or in which animals are confined~~ animal facilities.

~~b.~~ 2. **Seed treatment.** This category ~~includes commercial applicators using restricted use~~ authorizes the application or sale of pesticides on agricultural crop seeds, other seeds, and vegetative seed stocks.

~~c.~~ 3. **Fumigation.** This category includes ~~applicators using restricted use fumigants for~~ controlling pests in stored and transported agricultural crops, grain milling equipment, and storage facilities. ~~(Effective April 1, 1991, private applicators.)~~

~~d.~~ 4. **Ornamental and turf pest control.** This category includes ~~commercial applicators using restricted use~~ pesticides to control pests in the production and maintenance of ornamental trees, shrubs, flowers, and turf.

~~e.~~ 5. **Greenhouse.** This category includes ~~commercial applicators using restricted use~~ pesticides to control pests in a greenhouse.

~~f.~~ 6. **Right of way.** This category includes ~~commercial applicators using restricted use~~ pesticides to control pests in the maintenance of public roads, electric powerlines, pipelines, railways, right of ways, parking lots, or other similar areas.

~~g.~~ 7. **Public health pest control.** This category includes state, federal, or other government employees, or applicators working under government contract, using ~~restricted use~~ pesticides in public health programs for the management and control of pests having medical and public health impacts.

~~h.~~ 8. **Research and demonstration pest control.** This category ~~is for those~~ includes individuals who demonstrate or apply ~~restricted use~~ pesticides for education and research ~~or education or research~~. These would include county agents, extension specialists, state, federal, and commercial employees, plus other persons conducting research or demonstrating the proper application of restricted use pesticides.

~~i.~~ 9. **Home, industrial, and institutional pest control.** This category includes commercial applicators using ~~restricted use~~ pesticides in, on, or around food-handling establishments, human dwellings, public or private institutions, warehouses, grain elevators, and any other structures or adjacent area, for the control of pests.

~~j.~~ 10. **Wood preservatives.** This category includes commercial applicators who apply and treat with ~~restricted use~~ wood preservatives to preserve and protect wood, posts, and various lumber products from pests.

~~k.~~ 11. **Vertebrate.** This category includes commercial applicators who use ~~restricted use~~ pesticides for the control of certain pest vertebrate, such as rodents, certain predators, and bats.

~~l.~~ 12. **Metam-sodium.** This category includes commercial applicators who use or sell the restricted use pesticide metam-sodium (sodium N-methyldithiocarbamate dihydrate) for the purpose of controlling tree or other plant roots infesting sewer systems.

~~2. Commercial applicators and dealers.~~

~~a. A commercial applicator or dealer, or commercial applicator and dealer certificate shall be issued in accordance with North Dakota Century Code section 4-35-09 or 4-35-12 or sections 4-35-09 and 4-35-12 respectively, only to those persons who successfully complete the certification examination established by the board, and who pay the certification fee.~~

~~b. The board shall establish a certification examination which shall be administered by any North Dakota state university extension designate in accordance with North Dakota Century Code section 4-35-09 or 4-35-12 or sections 4-35-09 and 4-35-12. The examination shall be given by the North Dakota state university extension designate only to those persons who:~~

~~(1) Are eighteen years of age or older; and~~

(2) Complete a certificate application in such form as the board shall require.

c. Commercial applicator's or dealer or commercial applicator and dealer certificates shall expire on April first following the third anniversary of the year of certification or recertification. Every commercially certified person shall be recertified by an approved seminar or an approved examination at least every third year and must complete an approved examination at least every ninth year.

d. Any person who fails an examination may retake such examination after three or more days.

e. All commercial applicators must be certified in the proper category of application.

f. All dealers must be certified in the category of the labels' intended target site.

g. In situations in which the pesticide is labeled for more than one of the certification target sites, the dealer only needs to be certified in one of the categories.

3. **Private applicators**.

a. A private applicator certification shall be issued in accordance with North Dakota Century Code section 4-35-14 only to those persons who:

(1) Are eighteen years of age or older; and

(2) Demonstrate competence in the application of pesticides as provided in subdivisions b, c, d, and e.

b. Persons purchasing, storing, or applying restricted use grain fumigants must be commercially trained and must pass a fumigation examination. At the option of the applicant upon successfully passing the examination, the certificate issued will be for either private or commercial application of restricted use fumigants. The fee for the private and commercial certification will be set by the North Dakota state university extension service.

c. Competence to apply restricted use pesticides shall be demonstrated by a showing of any one of the following to the North Dakota state university extension designate in the applicant's area:

~~(1) Attendance at an approved educational seminar, signing of a certificate of attendance, and passing an examination.~~

~~(2) Completion of a course of self-instruction and passing an examination at the North Dakota state university extension designate's office in the applicant's area.~~

~~(3) Completion of a take-home self-study program and passing an examination.~~

~~(4) Passing the dealer or commercial applicator certification examination and submitting the passing grade to the appropriate North Dakota state university extension designate.~~

~~d. Every private applicator shall be recertified by an approved seminar or an approved examination at least every third year and must complete an approved examination at least every ninth year.~~

~~e. Competence to apply a single restricted use pesticide by a person who cannot read shall be demonstrated by completion of a course of oral instruction and completion of a procedure to determine teaching-learning effectiveness to the North Dakota state university extension designate in the applicant's area. Such private applicator certification for a single restricted use pesticide shall be for no more than one year and the notation "Restricted to" followed by the common name of the restricted use pesticide in bold lettering shall appear on the private applicator certificate.~~

~~f. In an emergency situation, competence to apply a single restricted use pesticide by a person shall be demonstrated by completion of a course of oral instruction and completion of a procedure to determine teaching-learning effectiveness to the North Dakota state university extension designate in the applicant's area. Such private applicator certification for a single restricted use pesticide shall expire sixty days from issuance and shall be issued to a person only once. The notation "Restricted to" followed by the common name of the restricted use pesticide shall appear on the private applicator certificate in bold lettering.~~

History: Amended effective February 1, 1982; October 1, 1990; November 1,1991; March 1, 1996; August 1, 2000; March 1, 2003.
General Authority: NDCC 4-35-06, 4-35-12
Law Implemented: NDCC 4-35-08, 4-35-09, 4-35-12, 4-35-14

60-03-01-05.1. Commercial applicator and dealer.

1. A commercial applicator or dealer, or commercial applicator and dealer certificate shall be issued in accordance with North Dakota Century

Code section 4-35-09 or 4-35-12 or sections 4-35-09 and 4-35-12 respectively, only to those persons who successfully complete the certification examination established by the board, and who pay the certification fee.

2. The board shall establish a certification examination which shall be administered by any North Dakota state university extension designate in accordance with North Dakota Century Code section 4-35-09 or 4-35-12. The examination shall be given by the North Dakota state university extension designate only to those persons who:

   a. Are eighteen years of age or older; and

   b. Complete a certificate application in such form as the board shall require.

3. Commercial applicators or dealer or commercial applicator and dealer certificates shall expire on April first following the third anniversary of the year of certification or recertification. Every commercially certified person shall be recertified by an approved seminar or an approved examination at least every third year.

4. Any person who fails an examination may retake such examination after three or more days.

5. All commercial applicators must be certified in proper category of application.

6. All dealers must be certified in the proper category of the labels.

7. If the pesticide is labeled for more than one of the certification target sites, the dealer only needs to be certified in one of the categories.

History: Effective March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-03-09, 4-35-12, 4-35-14

60-03-01-05.2. Private applicator certification.

1. A private applicator certification shall be issued in accordance with North Dakota Century Code section 4-35-14 only to those persons who:

   a. Are eighteen years of age or older; and

   b. Demonstrate competence in the application of pesticides.

2. Competence to apply restricted use pesticides shall be demonstrated by a showing of any one of the following to the North Dakota state university extension designate in the applicant's area:

   a. Attendance at an approved educational seminar, signing of a certificate of attendance, and passing an examination.

   b. Completion of a course of self-instruction and passing an examination at the North Dakota state university extension designate's office in the applicant's area.

   c. Completion of a take-home self-study program and passing an examination.

   d. Passing the dealer or commercial applicator certification examination and submitting the passing grade to the appropriate North Dakota state university extension designate.

3. Persons purchasing, storing, or applying restricted use grain fumigants must be commercially trained and must pass a fumigation examination. At the option of the applicant upon successfully passing the examination, the certificate issued will be for either private or commercial application of restricted use fumigants. The fee for the private and commercial certification will be set by the North Dakota state university extension service.

4. Every private applicator shall be recertified by an approved seminar or an approved examination at least every third year.

5. Any person who fails an examination may retake such examination after three or more days.

History: Effective March 1, 2003.
General Authority: NDCC 4-35-06, 4-35-12
Law Implemented: NDCC 4-35-08, 4-35-14

60-03-01-06. ~~Application, storage, transportation, and disposal of pesticides~~ Pesticide mixing, loading, and application - Storage - Transportation - Disposal.

1. ~~**Application**~~ **Mixing, loading, and application**.

   a. All pesticides shall be used in accordance with the label.

   b. Pesticide applications shall be made in a manner that prevents off-target discharges of pesticides.

c. Pesticide application or loading equipment that is designed to draw water from surface water shall have a properly functioning antisiphoning device attached to the inlet hose.

d. Applications shall not occur when the atmospheric conditions favor the off-target drift of pesticides or prevent the proper deposition of pesticides to the target area.

e. Pesticides shall be applied in a manner that minimizes the exposure to animals. Unless permitted by the labeling, an applicator shall take all reasonable precautions that will prevent a pesticide from being applied if unprotected persons are present within the application site or are present in adjacent areas when off-target drift may occur.

f. Pesticide applicators and persons assisting with an application shall follow all safety precautions as specified on the container label.

~~e.~~ g. All equipment used in pesticide mixing, loading, and application must be operationally sound and properly calibrated to prevent ~~unreasonable~~ adverse effects on the environment.

~~d.~~ h. Any commercial applicator who mixes, loads, or otherwise uses pesticides shall have immediate access to a spill kit at the loading site containing not less than two buckets, absorptive pillows, or another system for containing leaking nozzles or a pesticide spill. The spill kit requirement does not apply to a person who uses single containers of pre-mixed, ready-to-use pesticides.

i. All pesticides that require posting on the label under the environmental protection agency worker protection standard must be posted according to the environmental protection agency worker protection standard. In addition, the pesticides from the following list must be posted by the farm operator or the farm operator's cooperating designee, which may include commercial applicators.

(1) Methyl parathion.

(2) Ethyl parathion.

(3) Dyfonate postemergence foliar applications.

(4) Furadan postemergence foliar applications to corn, sorghum, and sunflowers.

(5) Di-syston postemergence foliar application to corn and sorghum.

Any pesticide applicator applying pesticides from this list for a farm operator is required to inform the farm operator within twenty-four hours in advance of the pesticide application, allowing the farm operator time to post the field before the application occurs. The farm operator is primarily responsible for posting the field. However, if the applicator does not contact the farm operator before the application, the applicator is responsible for posting the field. Pesticide applicators are responsible to inform farm operators if applications do not occur as scheduled.

There are two options for properly posting fields.

Option 1: The signs must be a minimum of eight inches by eleven inches [20.32 centimeters by 27.94 centimeters] with one-half-inch [1.270-centimeter] lettering and be easily readable. The signs must be posted at all normal entrances to the field and on all corners which are along normally traveled roads. These signs can be a maximum of one-half mile [.80 kilometer] apart. The signs must contain the following information: Danger - field sprayed with (pesticide name). The field is safe for reentry on (date).

Option 2: Flags used by aerial applicators when marking field areas that have been sprayed can be used for posting. Such flags must be at least four inches by eight feet [10.16 centimeters by 2.438 meters]. The lettering on the flags must be fluorescent with a white background and must be easily readable. The signs must be dropped outside the field boundaries within fifty feet [15.24 meters] of all normal entrances to the field and all corners along normally traveled roads. These signs can be a maximum of one-fourth mile [.402 kilometer] apart along normally traveled roads. The signs must contain the following language: DANGER - KEEP OUT - THIS FIELD SPRAYED WITH A PESTICIDE. BEFORE ENTRY, CONTACT (business name and ~~phone~~ telephone number).

The business name and ~~phone~~ telephone number can be printed on the flag or, if the flag gives directions to refer to the attached cardboard, the business name and ~~phone~~ telephone number can be printed on the cardboard.

Along with the lettering a skull and crossbones must be printed on the flag in a larger size than the largest lettering. The lettering for "Danger - Keep Out" must be at least three-fourths of an inch [1.905 centimeters]. The lettering for the remaining wording must be at least three-eighths of an inch [.953 centimeter].

2. **Storage.**

   a. All pesticides, except bulk pesticides, shall be stored in their original container and in accordance with label recommendations.

All labels of stored pesticides shall be plainly visible. All pesticide containers must have a proper label affixed to them.

b. All pesticides shall be stored in dry, well-ventilated spaces, and in a manner ~~which~~ that will not endanger humans, animals, or the environment, nor contaminate food or feed through a release or escape.

c. If a storage area contains a floor drain, it must be sealed or self-contained.

d. Pesticide storage areas must be marked at all entrances.

e. Label-specific safety equipment for all pesticides stored must be available at the immediate storage site.

f. Pesticides shall be secured in a manner to prevent children, unauthorized persons, or animals from gaining entry to the stored pesticides.

3. **Transportation**.

a. All pesticides, except bulk pesticides, shall be transported in their original containers. All pesticides must be transported in a secure manner to avoid breakage of containers, spills, or any other manner of contamination.

b. Pesticides shall not be transported with foodstuffs, feed, or any other product or material so as to pose a hazard to humans, animals, or the environment.

c. Equipment contaminated in the transportation of pesticides shall be cleaned and decontaminated prior to any other use.

4. **Disposal**.

a. Empty pesticide containers shall be stored in accordance with label recommendations and in a manner which will not endanger humans, animals, or the environment.

b. Empty nonreturnable pesticide containers shall be triple-rinsed or equivalent on the day of their use. Secondary use of such containers which would endanger humans, animals, or the environment is prohibited.

c. Pesticide containers shall be disposed of in accordance with label directions and in a manner which will not endanger humans, animals, or the environment.

History: Amended effective April 15, 1985; October 1, 1990; July 1,1992; May 1, 1994; March 1, 1996; March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06, 4-35-20

60-03-01-07. Recordkeeping - Dealers and commercial and custom applicators and private applicators.

1. **Dealers.** Every pesticide dealer shall keep separate, accurate, and complete records of all purchases and sales of restricted use pesticides and all pesticides used under section 18 ~~pesticides and restricted use pesticides~~ (emergency exemption) and section 24-c (special local needs) of FIFRA. The records shall include the following for each pesticide purchased or sold:

   a. Purchases.

      (1) Dealer's name and address.

      (2) Pesticide name.

      (3) ~~Volume~~ Quantity of pesticide.

      (4) Date pesticide was shipped or received.

      (5) Distributor's name (person from whom the pesticide was received).

   b. Sales.

      (1) Dealer's name and address and identification of person making the sale.

      (2) Name, address, certification number, and signature of private or commercial applicator.

      (3) Date of sale.

      (4) Trade name or common name and quantity of pesticide sold.

      (5) Running inventory by product.

      (6) Intended ~~application~~ site or crop of ~~purchaser~~ application for all pesticides used under section 18 ~~pesticides~~ of FIFRA.

2. **Commercial ~~and custom~~ applicators.** Commercial ~~and custom~~ applicators shall keep a record of all pesticide applications. A copy of the records must be provided to the client or the applicator must have on file a signed letter giving the applicator permission to keep the records for the client. The record shall include for each application:

   a. Name and address of the person for whom the pesticide was applied.

   b. Legal description of the land, grain bin identification, railcar number, or other description of where the pesticide was applied.

   c. Pest or pests controlled.

   d. ~~Time~~ Starting and completion time the pesticide was applied (month, day, year, and hour ~~of the day~~).

   e. Person who supplied the pesticide ~~which~~ that was applied.

   f. Specific trade name of the pesticide applied and environmental protection agency registration number of the restricted ~~used~~ pesticide that was applied.

   g. Direction and estimated velocity of the wind and the estimated temperature of the outdoor air at the time the pesticide was applied. This requirement shall not apply if a bait is used to attract the pest or pests or if the application is made indoors.

   h. Amount of pesticide used, including:

      (1) Pounds [kilograms] or gallons [liters] per acre [.40 hectare] of formulated product.

      (2) Percentage or pounds [kilograms] of active ingredient.

      (3) Pounds [kilograms] or gallons [liters] of tank mix applied per acre [.40 hectare].

   i. Specific crops, commodities, and total acreage [hectarage] or other common identifying unit of measure to which the pesticide was applied.

   j. Description of equipment used in application.

   k. Certification number of applicator, if any, and signature.

   l. Right-of-way applicators must record weather conditions and geographic location in two-hour increments.

m. The registrant name that appears on the product label.

3. **Private applicators.** Private applicators shall keep a record of all restricted use pesticide applications. The records must include for each application:

   a. Legal description of the land, grain bin identification ~~(~~for fumigant or grain protectant applications~~)~~, or other description of where the pesticide was applied.

   b. Time the pesticide was applied (month, day, year, ~~hours of the day~~ and hour).

   c. Specific trade name of the pesticide applied and environmental protection agency registration number of the restricted use pesticide that was applied.

   d. Amount of pesticide used, including:

      (1) Pounds [kilograms] or gallons [liters] per acre [.40 hectare] of formulated product.

      (2) Total amount of chemical applied.

   e. Specific crops, commodities, and total acreage [hectarage] or other common identifying unit of measure~~,~~ to which the pesticide was applied.

   f. Certification number of applicator, if any, and signature.

Records made pursuant to this section shall be completed and made available for inspection on the day the pesticide is applied.

History: Amended effective October 1, 1990; May 1, 1994; March 1,1996; March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06, 4-35-16

60-03-01-08. Unlawful acts. Repealed effective March 1, 2003. ~~The commissioner may, after opportunity for a hearing, take any appropriate administrative or judicial enforcement action against any person if the commissioner finds that such person has committed any of the following acts, each of which is declared to be a violation of this chapter:~~

~~1. Made false or fraudulent claims through any media, misrepresenting the effect of materials or methods to be utilized, or advertised a pesticide without reference to its classification.~~

2. Made a pesticide recommendation, application, or use inconsistent with the labeling or other restrictions prescribed by the board.

3. Applied materials known by the person to be ineffective or improper.

4. Operated faulty or unsafe equipment.

5. Operated in a faulty, careless, or negligent manner.

6. Neglected or, after notice, refused to comply with the provisions of North Dakota Century Code chapter 4-35 and this chapter, or of any lawful order of the commissioner.

7. Refused or neglected to keep and maintain the records required by this chapter, or to make reports when and as required.

8. Made false or fraudulent records, invoices, or reports.

9. Aided or abetted a certified or an uncertified person to evade the provisions of North Dakota Century Code chapter 4-35 or this chapter, or conspired with such a certified or uncertified person to evade the provisions of North Dakota Century Code chapter 4-35 or this chapter.

10. Knowingly made false statements during or after an inspection.

11. Impersonated any federal, state, county, or city inspector or official.

12. Distributed any restricted use pesticide to any person who is required by law or regulations promulgated under such law to be certified to use or purchase such restricted use pesticides unless such person or such person's agent to whom distribution is made is certified to use or purchase that kind of restricted use pesticide.

13. Bought, used, or supervised the use of any restricted use pesticide without first complying with the certification requirements of North Dakota Century Code chapter 4-35, unless otherwise exempted therefrom.

14. Refused or neglected to post fields as required by the label or as required by this chapter.

15. Refused or neglected to inform farm operators of the posting requirement as required by this chapter.

History: Amended effective October 1, 1990; May 1, 1994.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-15, 4-35-24

60-03-01-09. Reports of pesticide accidents. Any person who is involved in or causes a pesticide accident that results in ~~unreasonable~~ adverse effects on animals or the environment shall file a report to the commissioner ~~within twenty-four hours by letter or telephone (328-2232) the following information.~~ The report must be made within twenty-four hours after the accident. The report may be filed by letter, telephone, or electronic mail at the address or number identified in subsection 4 of section 60-01-01-01. The report must contain:

1. The name of the pesticide.
2. The amount of pesticide or tank mix, or both.
3. The location of the pesticide accident.
4. The time of accident (month, day, year, and hour ~~of the day~~).
5. The direction and estimated velocity of the wind and estimated temperature at the time of the accident, if outdoors.
6. Actions taken to remedy the adverse effects on ~~humans,~~ animals~~,~~ and the environment.

History: Effective February 1, 1982; amended effective March 1, 1996; March 1, 2003.
General Authority: NDCC 4-35-21
Law Implemented: NDCC 4-35-21

60-03-01-10. ~~Registration, packaging, repackaging, storage, and transportation~~ Labeling and relabeling of bulk pesticides ~~for each business location~~.

1. ~~**Registration - Establishment number requirements.**~~

   ~~a. Any person that repackages bulk pesticides must have an environmental protection agency establishment number.~~

   ~~b.~~ Any person that ~~makes~~ produces a ~~mix~~ mixture of any quantity of pesticide, to be applied by another person, and holds the ~~mix~~ mixture in inventory, must have an environmental protection agency establishment number.

   The person making the ~~mix~~ mixture must supply the person applying the ~~mix~~ mixture with end-use labeling for each pesticide in the ~~mix~~ mixture. The end-use labeling must have the facilities establishment number printed on it.

~~c.~~ 2. The environmental protection agency establishment number and end-use labeling must be attached to bulk pesticide storage tanks.

~~d.~~ 3. The environmental protection agency establishment number ~~and~~, end-use labeling, and quantity of pesticide repackaged must accompany or be attached to the mobile bulk pesticide container.

~~e.~~ 4. Any person that custom blends any quantity of pesticide to be applied by another person must ensure that end-use labeling for all pesticides in the blend accompanies the blend to the point of end use. No establishment number is required for the blending facilities.

~~2. **Storage and transportation.**~~

~~a. The transportation and storage of all bulk pesticides must be in compliance with the manufacturer's label requirements.~~

~~b. The transportation of bulk pesticides must meet all applicable standards of state and United States department of transportation rules and regulations.~~

~~c. Bulk pesticide storage containers must be made of materials and so constructed to be compatible with the pesticide stored and the conditions of storage, including any specifications that may appear on the pesticide labels and labeling.~~

~~d. Bulk storage containers and loading areas must be constructed and located on a site in a manner so that pesticides will not contaminate streams and water supplies.~~

~~e. All permanent bulk storage containers must be equipped with a locking withdrawal valve or must be stored in a secure locked area. The valves or storage area must be locked during nonbusiness hours.~~

~~f. Bulk pesticide storage containers that are going to be refilled with a different pesticide must be cleaned and rinsed according to both the repackager's and manufacturer's agreed upon written instructions and all former labeling must be removed.~~

~~3. **Liquid bulk pesticides.**~~

~~a. Outdoor storage:~~

~~(1) Liquid bulk pesticide storage containers must be on a site which has an additional containment structure. The structure must be constructed of sufficient size and material, approved by the pesticide registrant, so as to contain any spilled or discharged materials. Any outdoor liquid bulk pesticide storage facility constructed after June 5, 1992, must have a containment capacity of a minimum of one hundred~~

~~twenty-five percent of the single largest bulk pesticide storage container.~~

~~(2) Contaminated rainwater must be collected within this structure. Rainwater and contaminated rainwater cannot accumulate beyond twenty-five percent of the secondary containment's capacity or seven days, whichever comes first.~~

~~b. Indoor storage. Liquid bulk pesticide storage facilities located within an enclosed structure must be on a site which has an additional containment structure. The structure must be constructed of sufficient size and material, approved by the pesticide registrant, so as to contain any spilled or discharged materials. Any indoor liquid bulk pesticide storage facility must have a capacity of a minimum of one hundred ten percent of the single largest bulk pesticide storage container.~~

~~4. **Dry bulk pesticides.**~~

~~a. Outdoor storage facilities:~~

~~(1) Bulk dry pesticide storage facilities must have a six-inch [15.24-centimeter] high curb as an additional containment structure. No storage container may be placed closer than three feet [91.44 centimeters] from the curb. Except during loading, stored dry bulk pesticide must be covered by a roof or tarpaulin that will exclude precipitation from the pesticide. Storage containers must be placed on a concrete or other impervious surfaced floor, on pallets or on a raised platform to prevent water from contacting the pesticide.~~

~~(2) Contaminated rainwater must be collected within this structure. Rainwater and contaminated rainwater cannot accumulate beyond twenty-five percent of the secondary containment's capacity or seven days, whichever comes first.~~

~~b. Indoor storage facilities. Storage facilities located in an enclosed structure must have a minimum of a six-inch [15.24-centimeter] curb as an additional containment structure. No storage container may be placed closer than three feet [91.44 centimeters] from the curb, except where the curb is adjacent to a facility wall.~~

~~5. **Prohibitions.**~~

~~a. The transfer of bulk pesticides must be under the control of the repackager. Filling or refilling of containers is prohibited unless~~

~~they are capable of holding, in undivided quantities, the capacity as specified by the environmental protection agency.~~

~~b. Bulk pesticide storage containers may not be placed underground.~~

~~c. Repackaging at any location that does not have an environmental protection agency producer establishment number is prohibited except as provided in this subdivision. Repackaging bulk pesticides at an end-use site, such as a farm or field, which does not have an environmental protection agency producer establishment number can only be performed by a bulk pesticide retailer.~~

~~d. Repackaging of pesticides without the written agreement of the manufacturing company is prohibited.~~

~~e. Repackaging into improperly labeled containers is prohibited.~~

~~f. Repackaging into containers not designated as reusable by the chemical and container manufacturer is prohibited.~~

~~g. Containers used for repackaging must have a capacity as specified by the environmental protection agency or repackaging is prohibited.~~

~~h. Repackaging for resale from a nonpermanent bulk storage container is prohibited except as provided in this subdivision. Bulk pesticides can be repackaged at an end-use site, such as a farm or field, from a nonpermanent bulk storage container provided it is filled from a permanent bulk storage container at a bulk pesticide retailer's establishment or the pesticide registrant's establishment.~~

History: Effective April 15, 1985; amended effective October 1, 1990; July 1, 1992; May 1, 1994; January 1, 1997; March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06, 4-35-15, 4-35-20

60-03-01-11. Storage and transportation of bulk pesticides.

1. The transportation and storage of all bulk pesticides must be in compliance with the manufacturer's requirements.

2. The transportation of bulk pesticides must meet all applicable standards of state and United States department of transportation rules and regulations.

3. A bulk pesticide storage containers must be made of materials and so constructed to be compatible with the pesticide stored and the

conditions of storage, including any specifications that may appear on the pesticide labels and labeling.

4. A bulk storage container and loading areas must be constructed and located on a site in a manner so that pesticides will not contaminate streams and water supplies.

5. A permanent bulk storage container must be equipped with a locking withdrawal valve or must be stored in a secure locked area. The valves or storage area must be locked during nonbusiness hours or while unattended.

6. A bulk pesticide storage container that are going to be refilled with a different pesticide must be cleaned and rinsed according to both the repackager's and manufacturer's agreed-upon written instructions and all former labeling must be removed.

7. An outdoor permanent containment area must be constructed of sufficient size and material so as to contain any spilled or discharged materials. Minimum containment capacity shall be one hundred twenty-five percent of the single largest bulk pesticide storage container, or sufficient to recover and contain a volume of a four-inch rainfall, whichever is greater.

8. An indoor permanent containment area located within an enclosed structure must be constructed of sufficient size and material to contain any spilled or discharged materials, and approved by the pesticide registrant. Minimum containment capacity shall be one hundred ten percent of the single largest bulk pesticide storage container.

History: Effective March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06, 4-35-15

60-03-01-12. Packaging and repackaging requirements for liquid or dry bulk pesticides.

1. A person must obtain a repackaging agreement from the registrant prior to repackaging liquid or dry bulk pesticides.

2. Must be performed at a facility with an environmental protection agency establishment number.

3. Must use meters or scales, or both, compatible with the pesticide being repackaged.

4. Must be done in a permanent containment area with a primary shutoff valve or switch within immediate reach of the person who is engaged in the repackaging operation.

5. An operational area must be kept clean of clutter and not used as a storage area for items not immediately used for repackaging.

6. A spill kit must be located within fifty feet of an operational area.

7. Clean up of any spilled pesticide-containing materials must be performed immediately after the occurrence and reported according to local, state, and federal guidelines.

8. A pesticide or pesticide-containing material must be contained either by the permanent containment area itself or drained, pumped, or transferred to an additional impermeable, aboveground holding tank or reservoir until utilized or disposed of in compliance with applicable local, state, and federal laws. The holding tank or reservoir must be suitably constructed to prevent the release of pesticides or pesticide-containing materials to the environment.

History: Effective March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06, 4-35-15, 4-35-20

60-03-01-13. Prohibitions. No person may:

1. Package or repackage into a container unless the container is capable of holding, in undivided quantities, the capacity as specified by the environmental protection agency.

2. Place bulk pesticide storage containers underground.

3. Repackage into improperly labeled containers is prohibited.

4. Repackage into containers not designated as reusable by the registrant and container manufacturer is prohibited.

History: Effective March 1, 2003.
General Authority: NDCC 4-35-06
Law Implemented: NDCC 4-35-06, 4-35-15, 4-35-20