NORTH DAKOTA ADMINISTRATIVE CODE

VOLUME 3 of 3
(Pages 1 - 478)

Supplements 227 through 229

May 1998
June 1998
July 1998

Prepared by the Legislative Council staff
for the
Administrative Rules Committee

TABLE OF CONTENTS

TITLE 33

State Department of Health

MAY 1998

CHAPTER 33-07-01.1

33-07-01.1-03. Waiver provision. Rules adopted under North Dakota Century Code chapter 23-16 may be waived by the department for a specified period in specific instances, provided such a waiver does not adversely affect the health and safety of the patients and if compliance with the requirement would result in unreasonable hardship upon the hospital. ~~Requirements related to fire safety may only be considered for waiver by the department if approved in writing by the state fire marshal's office.~~

History: Effective April 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 23-01-03(3), 28-32-02
Law Implemented: NDCC 23-16-06

33-07-01.1-34. Obstetrical services.

1. All general acute hospitals providing obstetrical services shall provide for the admission, medical care, transfer, or discharge of obstetric and neonatal patients. Obstetrical services must include the following:

   a. The obstetrical services must have an organized obstetric staff with a chief of obstetrical services who is either certified or qualified in obstetrics or a physician who regularly practices obstetrics as head of the obstetrical service. The level of qualification and expertise of the chief of the obstetrical services must be appropriate to the level of care rendered in the hospital. Responsibilities of the chief of the obstetrical service include:

(1) The general supervision of the care of obstetrical patients.

(2) ~~The---identification---of---clinical--conditions--and procedures-requiring-consultation.~~

~~(3)~~ The arrangement of conferences held at regular intervals to review surgical procedures and operations, complications, and mortality.

~~(4)~~ (3) The provision for exchange of information between medical, administrative, and nursing staffs.

b. Only members of the medical staff with appropriate privileges may admit and care for patients in the obstetrical service areas. A roster of licensed health care practitioners, specifying the obstetrical privileges of each, must be maintained and available to staff in the obstetrical services area and in the files of the hospital administration.

c. Obstetrical patients under the effect of an analgesic or an anesthetic, in active labor or delivery, must be monitored and attended in accordance with the current standards of practice for obstetric-gynecologic services as identified by the association of women's health, obstetric and neonatal nursing and defined by hospital policies and procedures.

d. Fetal maturity must be established and documented prior to elective inductions and Caesarean sections.

e. There must be a written policy and procedure established in accordance with the current standards of practice as identified by the association of women's health, obstetric, and neonatal nursing concerning the administration and documentation of oxytocic drugs and their effects. Oxytocin may be used for medical induction or stimulation of labor only when qualified personnel, determined by the medical staff, can attend the patient closely. If electronic fetal monitoring is not available, the patient must be monitored on a one-to-one basis during the administration of the oxytocic drugs. The following areas must be included in the written policy and procedure for administration and documentation of oxytocic medications:

(1) The licensed health care practitioner shall evaluate the patient for induction or stimulation, especially with regard to indications for use of oxytocic medications.

(2) The licensed health care practitioner or other individuals starting the oxytocin shall be familiar with its effects and complications and be qualified to identify both maternal and fetal complications.

(3) A qualified licensed health care practitioner shall be immediately available as necessary to manage complications effectively.

f. Birthing and delivery rooms must be equipped and staffed to provide emergency resuscitation for infants in accordance with the current association of women's health, obstetric, and neonatal nursing standards of practice. Only personnel qualified and trained to do so may use infant emergency resuscitation equipment.

g. Equipment and personnel trained to use the equipment to maintain a neutral thermal environment for the neonate must be available and utilized as needed.

h. Nursing staff for obstetrical services must include:

(1) Nursing supervision by a registered nurse must be provided for the entire twenty-four-hour period the obstetrical services is occupied.

(2) At least one nurse trained in obstetrical and nursery care must be assigned to the care of mothers and infants at all times. Infants must be visually or electronically monitored at all times.

(3) A registered nurse must be in attendance at all deliveries, and must be available to monitor the mother's general condition and that of the fetus during labor.

i. A clean nursery must be provided near the mothers' rooms with adequate lighting and ventilation and must include the following:

(1) Bassinets equipped to provide for the medical examination of the newborn and for the storage of necessary supplies and equipment.

(2) A glass observation window through which infants may be viewed.

(3) Each nursery must have immediately on hand equipment necessary to stabilize the sick infant in accordance with current standards of practice established by the association of women's health, obstetric, and neonatal nursing and defined in hospital policies.

j. The hospital shall identify specific rooms and beds to be used exclusively for obstetrical patients, obstetrical and gynecological patients, and nursery patients as provided in a plan specifically approved by the department.

(1) Obstetrical services must be located and arranged to provide maximum protection for obstetrical and neonatal patients from infection and cross-infection from patients in other services of the hospital.

(2) Obstetrical services must be located in the hospital so as to prevent through traffic to any other part of the hospital.

2. Primary care hospitals may not provide obstetrical services.

3. If a specialized hospital provides obstetrical services, the specialized hospital is subject to the obstetrical services requirements for general acute hospitals.

History: Effective April 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 23-01-03(3), 28-32-02
Law Implemented: NDCC 23-16-06

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

1. "A_1" means the maximum activity of special form radioactive material permitted in a type A package. "A_2" means the maximum activity of radioactive material, other than special form ~~radioactive~~, low specific activity (LSA), and surface contaminated object (SCO) material, permitted in a type A package. These values are either listed in chapter 33-10-13, appendix A, table I, or may be derived in accordance with the procedure prescribed in chapter 33-10-13 appendix A.

2. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

3. "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectronvolt. For purposes of this definition, "particle accelerator" is an equivalent term.

4. "Accelerator produced material" means any material made radioactive by exposing it in a particle accelerator.

5. "Act" means North Dakota Century Code chapter 23-20.1.

6. "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

7. "Adult" means an individual eighteen or more years of age.

8. "Agreement state" means any state with which the United States nuclear regulatory commission has entered into an effective agreement under section 274(b) of the Atomic Energy Act of 1954, as amended [73 Stat. 688; 42 U.S.C. 2021].

9. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

10. "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

a. In excess of the derived air concentrations (DACs) specified in appendix B, table I of chapter 33-10-04.1, or

b. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of six-tenths percent of the annual limit on intake (ALI) or twelve derived air concentrations-hours.

11. "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by an offsite response organization to protect persons offsite.

12. "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

13. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the department.

14. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

15. "Bioassay" means the determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

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

17. "Byproduct material" means:

    a. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

    b. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

18. "Calendar quarter" means not less than twelve consecutive weeks nor more than fourteen consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by the licensee or registrant of determining calendar quarters for purposes of this article except at the beginning of a year.

19. "Calibration" means the determination of:

    a. The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

    b. The strength of a source of radiation relative to a standard.

20. "CFR" means Code of Federal Regulations.

21. "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids, ~~gluconic--acid;~~ and polycarboxylic acids <u>(e.g., citric acid, carbolic acid, and gluconic acid)</u>.

22. "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

23. "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the fifty-year period following the intake.

24. "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighing factors applicable to each of the

body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

25. "Constraint" (dose constraint) means a value above which specified licensee actions are required.

26. "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

27. "Curie" means a unit of measurement of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations or transformations per second (dps or tps).

~~26.~~ 28. "Decommission" means to remove ~~(as a facility)~~ or site safely from service and reduce residual radioactivity to a level that permits ~~release~~:

a. Release of the property for unrestricted use and termination of license~~.~~; or

b. Release of the property under restricted conditions and termination of the license.

~~27.~~ 29. "Deep dose equivalent" (H_d), which applies to external whole body exposure means the dose equivalent at a tissue depth of one centimeter (or a density thickness of 1000 mg/cm^2). This assumes a tissue density of one gram per cubic centimeter.

~~28.~~ 30. "Department" means the North Dakota department of health.

~~29.--"Depleted--uranium"-means-the-source-material-uranium-in-which the-isotope-uranium-235-is-less-than-0.711-weight--percent--of the--total-uranium-present.--Depleted-uranium-does-not-include special-nuclear-material.~~

31. "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

~~30.~~ 32. "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

~~31.~~ 33. "Dose equivalent (H_T)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

~~32.~~ 34. "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

~~33.~~ 35. "Effective does equivalent (H_E)" means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

~~34.~~ 36. "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~35.~~ 37. "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

~~36.~~ 38. "Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

~~37.~~ 39. "Exposure" means being exposed to ionizing radiation or to radioactive material.

~~38.~~ 40. "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

~~39.~~ 41. "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

~~40.~~ 42. "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of three-tenths centimeter (or a density thickness of 300 mg/cm^2). This assumes a tissue density of one gram per cubic centimeter.

~~41.~~ 43. "Former United States atomic energy commission or United States nuclear regulatory commission licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where their atomic energy commission or nuclear regulatory commission licenses have been terminated.

~~42.~~ 44. "Generally applicable environmental radiation standards" means standards issued by the United States environmental protection agency under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or

levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

~~43.~~ 45. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram [100 rad].

~~44.~~ 46. "Hazardous waste" means those wastes designated as hazardous by United States environmental protection agency regulations in 40 CFR part 261 and article 33-24 of the North Dakota Administrative Code.

~~45.~~ 47. "Healing arts" means diagnostic or healing treatment of human and animal maladies including, but not limited to, the following which are duly licensed by the state of North Dakota for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

~~46.~~ 48. "High radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of one hundred millirems [one millisievert] in one hour at thirty centimeters from any source of radiation or from any surface that the radiation penetrates.

~~47.~~ 49. "Human use" means the internal or external administration of radiation or radioactive material to human beings.

~~48.~~ 50. "Individual" means any human being.

~~49.~~ 51. "Individual monitoring" means the assessment of:

a. Dose equivalent by the use of individual monitoring devices or by the use of survey data; or

b. Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, derived air concentration-hours. (See the definition of derived air concentration-hours in chapter 33-10-04.1).

~~50.~~ 52. "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

~~51.~~ 53. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring

to determine compliance with rules, regulations, orders, requirements, and conditions of the department.

~~52.~~ 54. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

~~53.~~ 55. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

~~54.~~ 56. "License" means a general or specific license issued by the department in accordance with the regulations adopted by the department.

~~55.~~ 57. "Licensed material" means radioactive material received, possessed, used, transferred, or disposed of under a general or specific license issued by the department.

~~56.~~ 58. "Licensee" means any person who is licensed by the department in accordance with this article and North Dakota Century Code chapter 23-20.1.

~~57.~~ 59. "Licensing state" means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the conference of radiation control program directors, incorporated.

~~58.~~ 60. "Limits" (see "dose limits").

~~59.~~ 61. "Lost or missing licensed (or registered) source of radiation" means licensed (or registered) source of radiation whose location is unknown. This definition includes licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

62. "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228, or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten days.

~~60.~~ 63. "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding type A quantities as unsealed sources or material, or exceeding four times type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. The terms "type A quantity" and "type B quantity" are defined in chapter 33-10-13.

64. "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in chapter 33-10-07.

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

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

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

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

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

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

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

~~67.~~ 72. "Occupational dose" means the dose received by an individual in the course of employment~~,--while--engaged--in--activities licensed--or--registered--by--the--department,~~ in which the individual's assigned duties involve exposure to sources of radiation, whether or not the sources are in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, as ~~a-patient~~ from any medical ~~practices,~~ administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with subsection 12 of section 33-10-07-05, from voluntary

participation in medical research programs, or as a member of the public.

~~68.~~ 73. "Ore refineries" means all processors of a radioactive material ore.

~~69.~~ 74. "Package" means the packaging together with its radioactive contents as presented for transport.

75. "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this article. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

~~70.~~ 76. "Particle accelerator" (see "accelerator").

~~71.~~ 77. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the commission, or any successor thereto and other than federal government agencies licensed by the commission or any successor thereto.

~~72.~~ 78. "Personnel monitoring equipment" (see "individual monitoring devices").

~~73.~~ 79. "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

~~74.~~ 80. "Physician" means an individual licensed by this state to dispense drugs in the practice of medicine.

~~75.~~ 81. "Principal activities" means activities authorized by the license which are essential to achieving the purposes for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidential to decontamination or decommissioning are not principal activities.

~~76.~~ 82. "Public dose" means the dose received by a member of the public from sources of radiation from a licensed or registered operation. ~~It~~ Public dose does not include occupational dose, ~~dose~~ or doses received from background radiation, ~~dose received--as-a-patient-from-medical-practices~~ from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with subsection 12 of section 33-10-07-05, or ~~dose~~ from voluntary participation in medical research programs.

~~77.~~ 83. "Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below one hundred thirty degrees Fahrenheit [54.4 degrees Celsius] or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

~~78.~~ 84. "Quality factor" (Q) means the modifying factor, listed in tables I and II of section 33-10-01-14, that is used to derive dose equivalent from absorbed dose.

~~79.~~ 85. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of one hundred erg per gram or one one-hundredths joule per kilogram [0.01 gray].

~~80.~~ 86. "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high speed electrons, high speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

~~81.~~ 87. "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of five millirems [0.05 millisievert] in one hour at thirty centimeters from the source of radiation or from any surface that the radiation penetrates.

~~82.~~ 88. "Radiation dose" (see "dose").

~~83.~~ 89. "Radiation exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). (See section 33-10-01-14 units of radiation exposure, dose, and activity for the special unit equivalent "roentgen" (R).)

~~84.~~ 90. "Radiation exposure rate" means the radiation exposure per unit of time, such as R/min, mR/h, etc.

~~85.~~ 91. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

~~86.~~ 92. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection requirements.

~~87.~~ 93. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

~~88.~~ 94. "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

~~89.~~ 95. "Radiobioassay" (see "bioassay").

~~90.~~ 96. "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to this article and North Dakota Century Code chapter 23-20.1.

~~91.~~ 97. "Registration" means the notification of the department of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23-20.

~~92.~~ 98. "Regulations of the United States department of transportation" means the regulations in 49 CFR, 100-189.

~~93.~~ 99. "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert (Sv)).

~~94.~~ 100. "Research and development" means (a) theoretical analysis, exploration, or experimentation; or (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

101. "Residual radioactivity" means radioactivity in structures, materials, soils, ground water, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of this acticle.

~~95.~~ 102. "Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting

individuals against undue risks from exposure to sources of radiation. "Restricted area" does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

96. 103. "Roentgen" (R) means the special unit of exposure. One roentgen equals ~~2.58 x 10^{-4} coulombs~~ two hundred fifty-eight millionths of a coulomb per kilogram of air. (See "exposure")

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

98. 105. "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of seven one-thousandths centimeter (7 mg/cm^2) averaged over an area of one square centimeter.

99. 106. "SI" means the abbreviation for the international system of units.

~~100.~~107. "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

~~101.~~108. "Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

~~102.~~109. "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

~~103.~~110. "Source material" means: (a) uranium or thorium, or any combination thereof, in any physical or chemical form; or (b) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

~~104.~~111. "Source material milling" means any activity that results in the production of byproduct material as defined in subdivision b of subsection 17.

~~105.~~112. "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~106.~~113. "Special form radioactive material" means radioactive material that satisfies the following conditions:

a. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule.

b. The piece or capsule has at least one dimension not less than five millimeters [0.2 inch].

c. It satisfies the test requirements specified by the United States nuclear regulatory commission. A special form encapsulation designed in accordance with the United States nuclear regulatory commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the United States nuclear regulatory commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation ~~either~~ designed ~~or constructed~~ after ~~June 30, 1985,~~ March 31, 1996, or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

~~107.~~114. "Special nuclear material" means:

a. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the United States nuclear regulatory commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determined to be special nuclear material, but does not include source material; or

b. Any material artificially enriched by any of the foregoing but does not include source material.

~~108.~~115. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding three hundred fifty grams of contained U-235, uranium-233 in quantities not exceeding two hundred grams; plutonium in quantities not exceeding two hundred grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1", i.e., unity. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

~~109.~~116. "Surface contaminated object" (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. Surface contaminated objects must be in one of two groups with surface activity not exceeding the following limits:

a. Surface contaminated object-I (SCO-I): A solid object on which:

(1) The nonfixed contamination on the accessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred square centimeters) does not exceed four becquerels per square centimeter (0.0001 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or four-tenths becquerel per square centimeter (0.00001 microcurie/cm^2) for all other alpha emitters;

(2) The fixed contamination on the accessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred cm^2 does not exceed forty thousand becquerels per square centimeter (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or four thousand becquerels per square centimeter (0.1 microcurie/cm^2) for all other alpha emitters; and

(3) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred cm^2) does not exceed forty thousand becquerels per square centimeter (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or four thousand becquerel per square centimeter (0.1 microcurie/cm^2) for all other alpha emitters.

b. Surface contaminated object-II (SCO-II): A solid object on which the limits for surface contaminated object-I (SCO-I) are exceeded and on which:

(1) The nonfixed contamination on the accessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred cm^2) does not exceed four hundred becquerels per square centimeter (0.01 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or forty becquerels per square centimeter (0.001 microcurie/cm^2) for all other alpha emitters;

(2) The fixed contamination on the accessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred cm^2) does not exceed eight hundred thousand becquerels per square centimeter (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or eighty thousand becquerels per square centimeter (2 microcuries/cm^2) for all other alpha emitters; and

(3) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred cm^2) does not exceed eight hundred thousand becquerels per square centimeter (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or eighty thousand becquerels per square centimter (2 microcuries/cm^2) for all other alpha emitters.

~~109.~~ 117. "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes tests, physical examination, and measurements of levels of radiation or concentration of radioactive material present.

~~110.~~ 118. "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof. "Test" may also mean the process of verifying compliance with this article.

~~111.~~ 119. "These rules" means all parts of this article and any subsequent changes or additions thereto.

~~112.~~ 120. "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

~~113.~~ 121. "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in chapter 33-10-04.1 of these rules.

~~114.~~ 122. "United States department of energy" means the department of energy established by Public Law No. 95-91 [91 Stat. 565; 42 U.S.C. 7101 et seq.] to the extent that the department exercises functions formerly vested in the United States atomic energy commission, its chairman, members, officers, and components and transferred to the United States energy research and development administration and to the administrators thereof pursuant to sections 104(b), (c), and (d) of the Energy Reorganization Act of 1974 [Pub. L. 93-438; 88 Stat. 1237; 42 U.S.C. 5814, effective January 19, 1975] and

transferred to the secretary of energy pursuant to subsection 301(a) of the Department of Energy Organization Act [Pub. L. 95-91; 91 Stat. 577-578; 42 U.S.C. 7151, effective October 1, 1977].

~~115.~~ 123. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

~~116.~~ 124. "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

125. "Uranium" natural, depleted, enriched:

a. "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 percent by weight uranium-235, and the remainder by weight essentially uranium-238).

b. "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. Depleted uranium does not include special nuclear material.

c. "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

~~117.~~ 126. "Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act [Pub. L. 96-573; 94 Stat. 3347; 42 U.S.C. 2021b-2021j], as amended by Pub. L. 99-240 [99 Stat. 1842; 42 U.S.C. 2021b-2021j], effective January 15, 1986; that is, radioactive waste:

a. Not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in section 11e(2) of the Atomic Energy Act [Pub. L. 95-604; 92 Stat. 3033; 42 U.S.C. 2014(e)(2)] (uranium or thorium tailings and waste); and

b. Classified as low-level radioactive waste consistent with existing law and in accordance with subdivision a by the United States nuclear regulatory commission.

~~118.~~ 127. "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

~~119.~~ 128. "Week" means seven consecutive days starting on Sunday.

~~120.~~ 129. "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

~~121.~~ 130. "Worker" means an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant.

~~122.~~ 131. "Working level" (WL) means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of ~~1.3E+5~~ one hundred thirty thousand megaelectronvolt of potential alpha particle energy. The short-lived radon daughters are - for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

~~123.~~ 132. "Working level month" (WLM) means an exposure to one working level for one hundred seventy hours - two thousand working hours per year divided by twelve months per year is approximately equal to one hundred seventy hours per month.

~~124.~~ 133. "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 28-32-02, 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-01-14. Units of exposure, dose, and activity.

1. As used in these rules, the unit of exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to ~~2.58E-4~~ two hundred fifty-eight millionths coulomb per kilogram of air.

2. As used in these rules, the units of dose are:

   a. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of one hundred erg per gram or one one-hundredths (1/100) joule per kilogram (0.01 Gy).

   b. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad).

c. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

d. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

3. As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in table I.

Table I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENTS

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments, and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

4. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rem per hour or sievert per hour, as provided in subsection 3, one one-hundredth sievert [1 rem] of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of twenty-five million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from table II to convert a measured tissue dose in gray or rad to dose equivalent in rem or sievert.

Table II
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Fluence per Unit Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
(thermal) 2.5E-8	2	980E+6	980E+8
1E-7	2	980E+6	980E+8
1E-6	2	810E+6	810E+8
1E-5	2	810E+6	810E+8
1E-4	2	840E+6	840E+8
1E-3	2	980E+6	980E+8
1E-2	2.5	1010E+6	1010E+8
1E-1	7.5	170E+6	170E+8
5E-1	11	39E+6	39E+8
1	11	27E+6	27E+8
2.5	9	29E+6	29E+8
5	8	23E+6	23E+8
7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

5. For purposes of these rules, activity is expressed in the special unit of curie (Ci) or in the international system (SI) unit of becquerel (Bq), or their multiples, or disintegrations or transformations per unit of time.

   a. One curie (Ci) = 3.7E+10 disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm).

   b. One becquerel (Bq) = one disintegration or transformation per second (dps or tps).

6. SI numerical prefix conversions. See table III for a listing of numerical prefixes to convert SI units or special units by appropriate multiples:

Table III
SI Numerical Prefix Conversion Table

Multiplication Factors	Prefix	Symbol
1 000 000 000 000 000 000 = 10^{18}	exa	E
1 000 000 000 000 000 = 10^{15}	peta	P
1 000 000 000 000 = 10^{12}	tera	T
1 000 000 000 = 10^{9}	giga	G
1 000 000 = 10^{6}	mega	M
1 000 = 10^{3}	kilo	k
100 = 10^{2}	hecto	h
10 = 10^{1}	deka	da
0.1 = 10^{-1}	deci	d
0.01 = 10^{-2}	centi	c
0.001 = 10^{-3}	milli	m
0.000 001 = 10^{-6}	micro	u
0.000 000 001 = 10^{-9}	nano	n
0.000 000 000 001 = 10^{-12}	pico	p
0.000 000 000 000 001 = 10^{-15}	femto	f
0.000 000 000 000 000 001 = 10^{-18}	atto	a

History: Effective June 1, 1992; amended effective March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

33-10-02-02. Exemptions.

1. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, providing that the dose equivalent rate averaged over an area of ten square centimeters does not exceed ~~one-half millirem [5 microsievert]~~ five microsievert [0.5 millirem] per hour at five centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

2. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

3. Domestic television receivers are exempt from the requirements of this chapter.

History: Amended effective June 1, 1992; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04

CHAPTER 33-10-03

33-10-03-02. Exemptions.

1. **Source material.**

   a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one percent of the mixture, compound, solution, or alloy.

   b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided, that except as authorized in a specific license, such person shall not refine or process such ore.

   c. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers:

      (1) Any quantities of thorium contained in:

         (a) Incandescent gas mantles.

         (b) Vacuum tubes.

         (c) Welding rods.

         (d) Electric lamps for illuminating purposes provided that each lamp does not contain more than fifty milligrams of thorium.

         (e) Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium.

         (f) Rare earth metals and compounds, mixtures, and products containing not more than one-fourth of one percent by weight thorium, uranium, or any combination of these.

         (g) Personnel neutron dosimeters, provided that each dosimeter does not contain more than fifty milligrams of thorium.

      (2) Source material contained in the following products:

(a) Glazed ceramic tableware, provided that the glaze contains not more than twenty percent by weight source material.

(b) Glassware containing not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction.

(c) Glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

(d) Piezoelectric ceramic containing not more than two percent by weight source material.

(3) Photographic film, negatives, and prints containing uranium or thorium.

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that all of the following are met:

(a) The counterweights are manufactured in accordance with a specific license issued by the United States nuclear regulatory commission authorizing distribution by the licensee pursuant to 10 CFR 40.

(b) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM". This requirement need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM".

(c) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED". This requirement need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM".

(d) The exemption contained in this paragraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(a) The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM".

(b) The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of one-eighth inch [3.2 millimeters].

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than thirty percent by weight of thorium, and that the exemption contained in this paragraph shall not be deemed to authorize either:

(a) The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or

(b) The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than ~~five-thousandths-microcurie [185--becquerels]~~ <u>one hundred five becquerels [.005 microcurie]</u> of uranium.

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

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

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

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

2. **Radioactive material other than source material.**

a. Exempt concentrations.

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

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

b. Exempt quantities.

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

(2) This subdivision does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be

transferred to persons exempt under this subdivision or equivalent regulations of the United States nuclear regulatory commission, any agreement state, or a licensing state, except in accordance with a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.18 or by the department pursuant to subdivision b of subsection 5 of section 33-10-03-05 which license states that the radioactive material may be transferred by the licensee to persons exempt under this subdivision or the equivalent regulations of the United States nuclear regulatory commission, any agreement state, or a licensing state.

c. Exempt items.

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States nuclear regulatory commission, Washington, D.C. 20555):

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rates:

[1] ~~Twenty-five---------millicuries--------[925 megabecquerels]~~ Nine hundred twenty-five megabecquerels [25 millicuries] of tritium per timepiece.

[2] ~~Five--millicuries--[185-megabecquerels]~~ One hundred eighty-five megabecquerels [5 millicuries] of tritium per hand.

[3] ~~Fifteen--millicuries--[555--megabecquerels]~~ Five hundred fifty-five megabecquerels [15 millicuries] of tritium per dial (bezels when used shall be considered as part of the dial).

[4] ~~One------hundred------microcuries------[3.7 megabecquerels]~~ Three and seven-tenths megabecquerels [100 microcuries] of promethium-147 per watch or ~~two--hundred microcuries--[7.4-megabecquerels]~~ seven and four-tenths megabecquerels [200 microcuries] of promethium-147 per any other timepiece.

[5] ~~Twenty--microcuries--[0.74--megabecquerels]~~ Seventy-four hundredths megabecquerels [20 microcuries] of promethium-147 per watch hand or ~~forty--microcuries---[1.48 megabecquerels]~~ One and forty-eight hundredths megabecquerels [40 microcuries] of promethium-147 per other timepiece hand.

[6] ~~Sixty-microcuries-[2.22-megabecquerels]~~ Two and twenty-two hundredths megabecquerels [60 microcuries] of promethium-147 per watch dial or ~~one---hundred----twenty microcuries--[4.44-megabecquerels]~~ four and forty-four hundredths megabecquerels [120 microcuries] of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

[7] The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through fifty milligrams per square centimeter of absorber:

[a] For wristwatches, one-tenth millirad [1 microgray] per hour at ten centimeters from any surface.

[b] For pocket watches, one-tenth millirad [1 microgray] per hour at one centimeter from any surface.

[c] For any other timepiece, two-tenths millirad [2 micrograys] per hour at ten centimeters from any surface.

[8] ~~One--microcurie-[37-kilobecquerels]~~ Thirty-seven kilobecquerels [1 microcurie] of radium-226 per timepiece in timepieces acquired prior to October 1, 1982.

(b) Lock illuminators containing not more than ~~fifteen-millicuries--[555--megabecquerels]~~ five hundred fifty-five megabecquerels

[15 millicuries] of tritium or not more than ~~two millicuries---{74--megabecquerels}~~ seventy-four megabecquerels [2 millicuries] of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed one millirad [10 micrograys] per hour at one centimeter from any surface when measured through fifty milligrams per square centimeter of absorber.

(c) Balances of precision containing not more than ~~one-millicurie-{37-megabecquerels}~~ thirty-seven megabecquerels [1 millicurie] of tritium per balance or not more than ~~five-tenths--millicurie {18.5---megabecquerels}~~ eighteen and one-half megabecquerels [0.5 millicurie] of tritium per balance part.

(d) Automobile shift quadrants containing not more than ~~twenty-five------millicuries------{925 megabecquerels}~~ nine hundred twenty-five megabecquerels [25 millicuries] of tritium.

(e) Marine compasses containing not more than ~~seven hundred-fifty-millicuries-{27.75-gigabecquerels}~~ twenty-seven and seventy-five hundredths gigabecquerels [750 millicuries] of tritium gas and other marine navigational instruments containing not more than ~~two--hundred--fifty millicuries---{9.25---gigabecquerels}~~ nine and twenty-five hundredths gigabecquerels [250 millicuries] of tritium gas.

(f) Thermostat dials and pointers containing not more than ~~twenty-five----millicuries----{925 megabecquerels}~~ nine hundred twenty-five megabecquerels [25 millicuries] of tritium per thermostat.

(g) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

[1] ~~One---hundred---fifty---millicuries---{5.55 gigabecquerels}~~ Five and fifty-five hundredths gigabecquerels [150 millicuries] of tritium per microwave receiver protector tube or ~~ten-----millicuries----{370 megabecquerels}~~ three hundred seventy megabecquerels [10 millicuries] of tritium per any other electron tube.

[2] ~~One----microcurie----[37----kilobecquerels]~~ Thirty-seven kilobecquerels [1 microcurie] of cobalt-60.

[3] ~~Five--microcuries--[185-kilobecquerels]~~ One hundred eighty-five kilobecquerels [5 microcuries] of nickel-63.

[4] ~~Thirty--microcuries--[1.11--megabecquerels]~~ One and eleven hundredths megabecquerels [30 microcuries] of krypton-85.

[5] ~~Five--microcuries--[185-kilobecquerels]~~ One hundred eighty-five kilobecquerels [5 microcuries] of cesium-137.

[6] ~~Thirty--microcuries--[1.11--megabecquerels]~~ One and eleven hundredths megabecquerels [30 microcuries] of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material do not exceed ~~one-millirad [10-micrograys]~~ ten micrograys [1 millirad] per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

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

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

[2] Each instrument contains no more than ten exempt quantities. For purposes of this subparagraph an instrument's source may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this chapter,

provided that the sum of such fractions shall not exceed unity.

[3] For americium-241, ~~five-hundredths microcurie-[1.85--kilobecquerels]~~ one and eighty-five hundredths kilobecquerels [0.05 microcurie] is considered an exempt quantity under this subparagraph.

(i) Spark gap irradiators containing not more than ~~one-microcurie-[37-kilobecquerels]~~ thirty-seven kilobecquerels [1 microcurie] of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons [11.4 liters] per hour.

(2) Self-luminous products containing radioactive material.

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

(b) Radium-226. Any person is exempt from this article to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than ~~one-tenth--microcurie--[3.7 kilobecquerels]~~ three and seven-tenths kilobecquerels [0.1 microcurie] of radium-226 which were acquired prior to October 1, 1982.

(3) Gas and aerosol detectors containing radioactive material.

(a) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from this chapter to the extent that such person

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

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

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

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the United States nuclear

regulatory commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in 10 CFR 32.16 and 32.17 of the regulations of the United States nuclear regulatory commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.3, 23-20.1-04.4

33-10-03-04. General licenses.

1. **General licenses - source material.**

   a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than fifteen pounds [6.82 kilograms] of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of one hundred fifty pounds [68.2 kilograms] of source material in any one calendar year.

   b. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in subdivision a are exempt from the provisions of chapters 33-10-04.1 and 33-10-10 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this chapter.

   c. Persons who receive, possess, use, or transfer source material pursuant to the general license in subdivision a are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the department in a specific license.

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

e. Depleted uranium in industrial products and devices.

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

(2) The general license in paragraph 1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to subdivision a of subsection 5 of section 33-10-03-05 or in accordance with a specific license issued to the manufacturer by the United States nuclear regulatory commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the United States nuclear regulatory commission or an agreement state.

(3) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph 1 shall file form SFN 16092 "registration certificate - use of depleted uranium under general license" with the department. The form shall be submitted within thirty days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish the following information and such other information as may be required by that form:

[1] Name and address of the registrant.

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

[3] Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in item 2 of subparagraph a.

(b) The registrant possessing or using depleted uranium under the general license established by

paragraph 1 shall report in writing to the department any changes in information furnished by the registrant in form SFN 16092 "registration certificate - use of depleted uranium under general license". The report shall be submitted within thirty days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph 1:

(a) May not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(b) May not abandon such depleted uranium.

(c) Shall transfer or dispose of such depleted uranium only by transfer in accordance with subsection 12 of section 33-10-03-05. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph 1, the transferor shall furnish the transferee a copy of this article and a copy of form SFN 16092. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the United States nuclear regulatory commission's or agreement state's regulation equivalent to paragraph 1, the transferor shall furnish the transferee a copy of this article and a copy of form SFN 16092 accompanied by a note explaining that use of the product or device is regulated by the United States nuclear regulatory commission or agreement state under requirements substantially the same as those in this article.

(d) Within thirty days of any transfer, shall report in writing to the department the name and address of the person receiving the depleted uranium pursuant to such transfer.

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

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph 1 is exempt from the requirements of chapters 33-10-04.1 and 33-10-10 with respect to the depleted uranium covered by that general license.

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

a. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the United States nuclear regulatory commission for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of sections 33-10-01-06 through 33-10-01-11, paragraph 2 of subdivision a of subsection 2 of section 33-10-03-02, subsections 7, 12, and 13 of section 33-10-03-05, and chapters 33-10-04.1, 33-10-10, and 33-10-13. (Attention is directed particularly to the provisions of chapter 33-10-04.1 which relate to the labeling of containers.)

(1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than ~~five--hundred--microcuries [18.5---megabecquerels]~~ eighteen and five-tenths megabecquerels [500 microcuries] of polonium-210 per device.

(2) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than ~~five----hundred----microcuries----[18.5 megabecquerels]~~ eighteen and five-tenths megabecquerels [500 microcuries] of polonium-210 per device or a total of not more than ~~fifty-millicuries [1.85-gigabecquerels]~~ one and eighty-five hundredths gigabecquerels [50 millicuries] of hydrogen-3 (tritium) per device.

b. Certain measuring, gauging, and controlling devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use, or transfer in accordance with the provisions of

paragraphs 2, 3, and 4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in paragraph 1 applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to subdivision d of subsection 5 of section 33-10-03-05 or in accordance with the specifications contained in a specific license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state which authorizes distribution of devices to persons generally licensed by the nuclear regulatory commission, an agreement state, or a licensing state. (Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.)

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in paragraph 1:

(a) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels.

(b) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

[1] Devices containing only krypton need not be tested for leakage of radioactive material.

[2] Devices containing only tritium or not more than ~~one---hundred----microcuries----[3.7 megabecquerels]~~ three and seven-tenths megabecquerels [100 microcuries] of other beta or gamma emitting material or ~~ten~~

~~microcuries-[0.37--megabecquerels]~~ thirty-seven hundredths megabecquerels [10 microcuries] of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(c) Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

[1] In accordance with the instructions provided by the labels; or

[2] By a person holding a specific license from the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to perform such activities.

(d) Shall maintain records showing compliance with the requirements of subparagraphs b and c. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by subparagraph b must be maintained for two years after the required leak test is performed. Records of tests of the on-off mechanism and indicator required by subparagraph b must be maintained for two years after the required test of the on-off mechanism and indicator is performed. Records which are required by subparagraph c must be maintained for a period of two years from the date of the recorded event.

(e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of ~~five-thousandths microcurie-[185-becquerels]~~ one hundred eighty-five becquerels [0.005 microcurie] or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from

the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within thirty days, furnish to the department a report containing a brief description of the event and the remedial action taken.

(f) Shall not abandon the device containing radioactive material.

(g) Except as provided in subparagraph h, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the United States nuclear regulatory commission, an agreement state, or a licensing state whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device.

(h) Shall transfer the device to another general licensee only:

[1] Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this chapter and any safety documents identified in the label on the device and within thirty days of the transfer, report to the department the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name or position of an individual who may constitute a point of contact between the department and the transferee; or

[2] Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(i) Shall comply with the provisions of subsections 1, 2, 3, and 5 of section

33-10-04.1-16 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of chapters 33-10-04.1 and 33-10-10.

(4) The general license in paragraph 1 does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in paragraph 1 is subject to the provisions of sections 33-10-01-06 through 33-10-01-11, subsections 7, 12, and 13 of section 33-10-03-05, and chapter 33-10-13.

c. Luminous safety devices for aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided all of the following are met:

(a) Each device contains not more than ~~ten curies [370 gigabecquerels]~~ three hundred seventy gigabecquerels [10 curies] of tritium or ~~three hundred millicuries [11.1 gigabecquerels]~~ eleven and one-tenths gigabecquerels [300 millicuries] of promethium-147.

(b) Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the United States nuclear regulatory commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.53 of the regulations of the United States nuclear regulatory commission.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to paragraph 1 shall comply with the provisions of subsections 1, 2, 3, and 5 of section 33-10-04.1-16 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of chapters 33-10-04.1 and 33-10-10.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of sections 33-10-01-06 through 33-10-01-11, subsections 7, 12, and 13 of section 33-10-03-05, and chapter 33-10-13.

d. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

e. Calibration and reference sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs 4 and 5, americium-241 in the form of calibration or reference sources:

(a) Any person who holds a specific license issued by the department which authorizes the person to receive, possess, use, and transfer radioactive material.

(b) Any person who holds a specific license issued by the United States nuclear regulatory commission which authorizes the person to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs 4 and 5 to any person who holds a specific license issued by the department which authorizes the person to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of paragraphs 4 and 5 to any person who holds a specific license issued by the department which authorizes the person to receive, possess, use, and transfer radioactive material.

(4) The general licenses in paragraphs 1, 2, and 3 apply only to calibration or reference sources which have

been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States nuclear regulatory commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39 of the regulations of the United States nuclear regulatory commission.

(5) The general licenses provided in paragraphs 1, 2, and 3 are subject to the provisions of sections 33-10-01-06 through 33-10-01-11, subsections 7, 12, and 13 of section 33-10-03-05, and chapters 33-10-04.1, 33-10-10, and 33-10-13. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) Shall not possess at any one time, at any one location of storage or use, more than ~~five microcuries--[185--kilobecquerels]~~ one hundred eighty-five kilobecquerels [5 microcuries] of americium-241, ~~five-----microcuries-----[185 kilobecquerels]~~ one hundred eighty-five kilobecquerels [5 microcuries] of plutonium, or ~~five--microcuries---[185---kilobecquerels]~~ one hundred eighty-five kilobecquerels [5 microcuries] of radium-226 in such sources.

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

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

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

_____

Name of manufacturer or importer

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

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

(c) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the department, the United States nuclear regulatory commission, an agreement state, or a licensing state to receive the source.

(d) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage.

(e) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

f. General license for use of radioactive material for certain in vitro clinical or laboratory testing. (The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the

provisions of paragraphs 2, 3, 4, 5, and 6, the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(a) Carbon-14, in units not exceeding ~~ten microcuries-[370-kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(b) Cobalt-57, in units not exceeding ~~ten microcuries-[370-kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(c) Hydrogen-3 (tritium), in units not exceeding ~~fifty-microcuries-[1.85-megabecquerels]~~ one and eighty-five hundredths megabecquerels [50 microcuries] each.

(d) Iodine-125, in units not exceeding ~~ten microcuries-[370-kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(e) Mock iodine-125 reference or calibration sources, in units not exceeding ~~five-hundredths microcurie--[185-becquerels]~~ one hundred eighty-five becquerels [0.005 microcurie] of iodine-129 and ~~five-thousandths-microcurie-[185 becquerels]~~ one hundred eighty-five becquerels [0.005 microcurie] of americium-241 each.

(f) Iodine-131, in units not exceeding ~~ten microcuries-[370-kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(g) Iron-59, in units not exceeding ~~twenty microcuries-[740-kilobecquerels]~~ seven hundred forty kilobecquerels [20 microcuries] each.

(h) Selenium-75, in units not exceeding ~~ten microcuries-[370-kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(2) No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by paragraph 1 until the person has filed Department Form SFN 8423, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the department and received from the department a validated copy of Department Form SFN 8423 with certification number assigned. The physician, veterinarian, clinical laboratory, or

hospital shall furnish on Department Form SFN 8423 the following information and such other information as may be required by that form:

(a) Name and address of the physician, veterinarian, clinical laboratory, or hospital.

(b) The location of use.

(c) A statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in paragraph 1 and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by paragraph 1 shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in paragraph 1, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of ~~two--hundred--microcuries--[7.4--megabeequerels]~~ seven and four-tenths megabecquerels [200 microcuries].

(b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(c) The general licensee shall use the radioactive material only for the uses authorized by paragraph 1.

(d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States nuclear regulatory commission, any agreement state, or a licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(e) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in subparagraph e of paragraph 1 as required by subsection 1 of section 33-10-04.1-14.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to paragraph 1:

(a) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the United States nuclear regulatory commission, any agreement state, or a licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under this subdivision or its equivalent; and

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

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

_____
Name of manufacturer

[2] This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not

involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to this article and a general license of a licensing state.

_____
Name of manufacturer

(5) The physician, veterinarian, clinical laboratory, or hospital possessing or using radioactive material under the general license of paragraph 1 shall report, in writing, to the department, any changes in the information furnished by the physician, veterinarian, clinical laboratory, or hospital in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form SFN 8423. The report shall be furnished within thirty days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of paragraph 1 is exempt from the requirements of chapters 33-10-04.1 and 33-10-10 with respect to radioactive material covered by that general license. However, persons using mock iodine-125 reference or calibration sources described in subparagraph e of paragraph 1 shall comply with the provisions of subsection 1 of section 33-10-04.1-14 and subsections 1, 2, 3, and 5 of section 33-10-04.1-16.

g. Ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than ~~fifty-microcuries-[1.85 megabecquerels]~~ one and eighty-five hundredths megabecquerels [50 microcuries] of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the United States nuclear regulatory commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection

devices pursuant to the general license in paragraph 1:

(a) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the United States nuclear regulatory commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of subsection 1 of section 33-10-04.1-14.

(b) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon.

(c) Are exempt from the requirements of chapters 33-10-04.1 and 33-10-10 except that such persons shall comply with the provisions of subsection 1 of section 33-10-04.1-14, and subsections 1, 2, 3, and 5 of section 33-10-04.1-16.

(3) This general license does not authorize the manufacture, assembly, disassembly, or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of sections 33-10-01-06 through 33-10-01-11, subsections 7, 12, and 13 of section 33-10-03-05, and chapter 33-10-13.

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

33-10-03-05. Specific licenses.

1. **Filing application for specific licenses.**

   a. Applications for specific licenses shall be filed on a form prescribed by the department.

   b. The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application should be

granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the department provided such references are clear and specific.

f. Applications and documents submitted to the department shall be made available for public inspection except that the department may withhold any document or part thereof which is protected from disclosure by state and federal law or rule, including protection of trade secrets and individual medical records, as afforded by North Dakota Century Code section 23-20.1-09.1 from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

g. Each application for a specific license shall be accompanied by the fee prescribed in chapter 33-10-11.

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

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this article in such a manner as to minimize danger to public health and safety or property.

b. The applicant has a permanent in-state office.

c. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property.

d. The issuance of the license will not be inimical to the health and safety of the public.

e. The applicant satisfies any applicable special requirements in subsections 3, 4, 5, or 14, and in chapters 33-10-05, 33-10-07, and 33-10-12.

f. Environmental report, commencement of construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the department determines will significantly affect the quality of the environment, the department, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

g. Financial surety arrangements for site reclamation.

(1) Pursuant to North Dakota Century Code section 23-20.1-04.2 and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in paragraph 4 shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the North Dakota Century Code and this article.

(a) The amount of funds to be ensured by such surety arrangements shall be based on department-approved cost estimates.

(b) Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

(2) The arrangements required in paragraph 1 shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

(3) The following specific licensees are required to make financial surety arrangements:

(a) Major processors.

(b) Waste handling licensees.

(c) Former United States atomic energy commission or United States nuclear regulatory commission licensed facilities.

(d) Source material milling operations.

(e) All others except persons exempt pursuant to paragraph 5.

(4) For source material milling operations, the amount of funds to be ensured by such surety arrangements shall be based on department-approved cost estimates in an approved plan for (a) decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and (b) the reclamation of tailings or waste disposal areas in accordance with the technical criteria delineated in chapter 33-10-03. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. In addition, the surety shall cover the payment of the charge for long-term surveillance and control required by the department. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the department may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other federal or state agencies or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the

decommission and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the department to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time, e.g., five years, yet which must be automatically renewed unless the surety notifies the beneficiary (the department) and the principal (the licensee) some reasonable time, e.g., ninety days, prior to the renewal date of their intention not to renew. In such a situation the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least sixty days for the department to collect.

(5) The following persons are exempt from the requirements of paragraph 1:

(a) All state, local, or other government agencies, unless they are subject to subparagraph b of paragraph 3.

(b) Persons authorized to possess no more than one thousand times the quantity specified in Schedule B, exempt quantities, or combination of radioactive material listed therein as given in Schedule B.

(c) Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source.

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

(6) As provided by subsection 14 of section 33-10-03-05, certain applications for specific licenses must contain a proposed decommissioning funding plan or a certificate of financial assurance for decommissioning. In the case of renewal applications submitted before January 1, 1994, this submittal may follow the renewal application but must be submitted on or before January 1, 1994.

h. Long-term care requirements. Pursuant to North Dakota Century Code section 23-20.1-04.2, and as otherwise provided, a long-term care trust fund shall be established by the following specific licensees prior to the issuance of the license. (Long-term care funding may also be required for former United States atomic energy commission or United States nuclear regulatory commission licensed facilities.)

(1) Waste handling licensees.

(2) Source material milling licensees.

i. Continued surveillance requirements for source material mills.

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

(2) A minimum charge of two hundred fifty thousand dollars (1978 dollars) to cover the costs of long-term surveillance shall be paid by each mill operator to the department prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific

evaluation, to be significantly greater than those specified in paragraph 1, e.g., if fencing is determined to be necessary, variance in funding requirements may be specified by the department. The total charge to cover the costs of long-term surveillance shall be such that, with an assumed one percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The charge will be adjusted annually prior to actual payments to recognize inflation. The inflation rate to be used is that indicated by the change in the consumer price index published by the United States department of labor, bureau of labor statistics.

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

   a. Use of sealed sources in industrial radiography. In addition to the requirements set forth in subsection 2, a specific license for use of sealed sources in industrial radiography will be issued if all of the following are met:

      (1) The applicant will have an adequate program for training radiographic personnel and submits to the department a schedule or description of such program which specifies the:

         (a) Initial training.

         (b) Periodic training.

         (c) On-the-job training.

         (d) Means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with this article and licensing requirements, and the operating and emergency procedures of the applicant.

      (2) The applicant has established and submits to the department satisfactory written operating and emergency procedures described in subsection 2 of section 33-10-05-06.

      (3) The applicant will have an internal inspection system adequate to assure that this article, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system must include the performance of internal inspections at intervals not

to exceed three months and the retention of records of such inspections for two years.

(4) The applicant submits to the department a description of the applicant's overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.

(5) The applicant who desires to conduct the applicant's own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the department a description of such procedures including:

(a) Instrumentation to be used.

(b) Method of performing tests.

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

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

b. Possession of radioactive materials in unsealed form on foils or plated sources or sealed in glass in excess of the quantities in Schedule E "quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release". In addition to the requirements set forth in subsection 2, a specific license for the possession of large quantities of radioactive materials in unsealed form on foils or plated sources or sealed in glass will be issued if either of the following are submitted and approved by the department:

(1) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials should not exceed ~~one-rem~~ ten millisieverts [1 rem] effective dose equivalent or ~~five-rems~~ fifty millisieverts [5 rems] to the thyroid; or

(2) An emergency plan for responding to a release of radioactive material.

(3) One or more of the following factors may be used to support an evaluation submitted under paragraph 1:

(a) The radioactive material is physically separated so that only a portion could be involved in an accident;

(b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(c) The release fraction in the respirable size range would be lower than the release fraction shown in Schedule E due to the chemical or physical form of material;

(d) The solubility of the radioactive material would reduce the dose received;

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule E;

(f) Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule E; or

(g) Other factors appropriate for the specific facility.

(4) An emergency plan for responding to a release of radioactive material submitted under paragraph 2 must include the following information:

(a) Facility description. A brief description of the licensee's facility and area near the site.

(b) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(c) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(d) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(e) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(f) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(g) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the department; also responsibilities for developing, maintaining, and updating the plan.

(h) Notification and coordination. A commitment to a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(i) Information to be communicated. A brief description of the type of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the department.

(j) Training. A brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(k) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(l) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(m) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(5) The licensee shall allow the offsite response organizations expected to respond in case of an accident sixty days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the sixty days to the department with the emergency plan.

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

from the United States nuclear regulatory commission, Washington, D.C. 20555.)

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

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

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

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

b. An application for a type A specific license of broad scope will be approved if all of the following are met:

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

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material.

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

(a) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material.

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

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

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

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

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

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

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

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material

control and accounting, and management review that are necessary to assure safe operations, including:

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

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

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

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

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

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

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

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

(a) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering.

(b) At least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to this subsection shall not:

(a) Conduct tracer studies in the environment involving direct release of radioactive material.

(b) Receive, acquire, own, possess, use, or transfer devices containing ~~one-hundred--thousand--curies [3.7---petabecquerels]~~ three and seven-tenths petabecquerels [100,000 curies] or more of radioactive material in sealed sources used for irradiation of materials.

(c) Conduct activities for which a specific license issued by the department under subdivision a of subsection 3, subsection 5, or chapter 33-10-07, is required.

(d) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each type A specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each type B specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

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

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

a. Licensing the introduction of radioactive material into products in exempt concentrations.

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

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

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

(2) Each person licensed under this subsection shall file an annual report with the department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into

each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of the radioactive material have been made pursuant to this subdivision during the reporting period, the report shall so indicate. The report shall cover the year ending June thirtieth, and shall be filed within thirty days thereafter.

b. Licensing the distribution of radioactive material in exempt quantities. (Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States nuclear regulatory commission, Washington, D.C. 20555.)

(1) An application for a specific license to distribute naturally occurring and accelerator-produced radioactive material to persons exempted from this article pursuant to subdivision b of subsection 2 of section 33-10-03-02 will be approved if all of the following are met:

(a) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.

(b) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

(c) The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.

(2) The license issued under paragraph 1 is subject to the following conditions:

(a) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt

quantity provided the sum of the fractions shall not exceed unity.

(b) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to subdivision b of subsection 2 of section 33-10-03-02. The outer package shall be such that the dose rate at the external surface of the package does not exceed ~~one-half-millirem [5-----microsieverts]~~ five microsieverts [0.5 millirem] per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which (1) identifies the radionuclide and the quantity of radioactivity, and (2) bears the words "radioactive material".

(d) In addition to the labeling information required by subparagraph c, the label affixed to the immediate container, or an accompanying brochure, shall (1) state that the contents are exempt from licensing state requirements; (2) bear the words "radioactive material - not for human use - introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited - exempt quantities should not be combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3) Each person licensed under this subdivision shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under subdivision b of subsection 2 of section 33-10-03-02 or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June thirtieth, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to this subdivision during the reporting period, the report shall so indicate.

c. Licensing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors. An application for a specific license authorizing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors to be distributed to persons exempt under paragraph 3 of subdivision c of subsection 2 of section 33-10-03-02 will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device may not exceed ~~one-tenth---microcurie--[3.7 kilobecquerels]~~ three and seven-tenths kilobecquerels [0.1 microcurie].

d. Licensing the manufacture and distribution of devices to persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04.

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory commission, an agreement state, or a licensing state will be approved if:

(a) The applicant satisfies the general requirements of subsection 2 of this section.

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

[1] The device can be safely operated by persons not having training in radiological protection.

[2] Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year a dose in excess of ten percent of the limits specified in subsection 1 of section 33-10-04.1-06.

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

[a]	Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems [150 milli-sieverts]
[b]	Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	200 rems [2 sieverts]
[c]	Other organs	50 rems [500 milli-sieverts]

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

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

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

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

[a] The receipt, possession, use, and transfer of this device Model ____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the United States

nuclear regulatory commission or a state with which the United States nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. (The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.) This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____
(name of manufacturer or distributor)

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

CAUTION-RADIOACTIVE MATERIAL

_____
(name of manufacturer or distributor)

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

department will consider information which includes, but is not limited to:

(a) Primary containment or source capsule.

(b) Protection of primary containment.

(c) Method of sealing containment.

(d) Containment construction materials.

(e) Form of contained radioactive material.

(f) Maximum temperature withstood during prototype test.

(g) Maximum pressure withstood during prototype tests.

(h) Maximum quantity of contained radioactive material.

(i) Radiotoxicity of contained radioactive material.

(j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under subdivision b of subsection 2 of section 33-10-03-04, or under equivalent regulations of the United States nuclear regulatory commission, an agreement state, or a licensing state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar year dose in excess of ten percent of the limits specified in subsection 1 of section 33-10-04.1-06.

(4) Each person licensed under subdivision d to distribute devices to generally licensed persons shall:

(a) Furnish a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04 to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in subdivision b of subsection 2 of section 33-10-03-04.

(b) Furnish a copy of the general license contained in the United States nuclear regulatory commission's, agreement state's, or licensing state's regulation equivalent to subdivision b of subsection 2 of section 33-10-03-04, or alternatively, furnish a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04 to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the United States nuclear regulatory commission, the agreement state, or the licensing state. If a copy of the general license in subdivision b of subsection 2 of section 33-10-03-04 is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the United States nuclear regulatory commission, agreement state or licensing state under requirements substantially the same as those in subdivision b of subsection 2 of section 33-10-03-04.

(c) Report to the department all transfers of such devices to persons for use under the general license in subdivision b of subsection 2 of section 33-10-03-04. Such report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04 during the reporting period,

the report shall so indicate. The report shall cover each calendar quarter and shall be filed within thirty days thereafter.

(d) Furnish reports to other agencies.

[1] Report to the United States nuclear regulatory commission all transfers of such devices to persons for use under the United States nuclear regulatory commission general license in 10 CFR 31.5.

[2] Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to subdivision d for use under a general license in that state's regulations equivalent to subdivision b of subsection 2 of section 33-10-03-04.

[3] Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within thirty days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

[4] If no transfers have been made to United States nuclear regulatory commission licensees during the reporting period, this information shall be reported to the United States nuclear regulatory commission.

[5] If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of the agency.

(e) Keep records showing the name, address, and the point of contact for each general licensee to

whom the licensee directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in subdivision b of subsection 2 of section 33-10-03-04, or equivalent regulations of the United States nuclear regulatory commission or an agreement state or a licensing state. The records should show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this paragraph.

e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under subdivision c of subsection 2 of section 33-10-03-04 will be approved if:

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

(2) The applicant satisfies the requirements of 10 CFR 32.53, 32.54, 32.55, 32.56, and 32.101 or their equivalent.

f. Special requirements for license to manufacture calibration sources containing americium-241, plutonium, or radium-226 for distribution to persons generally licensed under subdivision e of subsection 2 of section 33-10-03-04. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium, or radium-226 to persons generally licensed under subdivision e of subsection 2 of section 33-10-03-04 will be approved if:

(1) The applicant satisfies the general requirement of subsection 2 of this section.

(2) The applicant satisfies the requirements of 10 CFR 32.57, 32.58, 32.59, and 32.102 and 10 CFR 70.39 or their equivalent.

g. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of subdivision f of subsection 2 of section 33-10-03-04 will be approved if:

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

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Carbon-14 in units not exceeding ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(b) Cobalt-57 in units not exceeding ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(c) Hydrogen-3 (tritium) in units not exceeding ~~fifty microcuries [1.85 megabecquerels]~~ one and eighty-five hundredths megabecquerels [50 microcuries] each.

(d) Iodine-125 in units not exceeding ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(e) Mock iodine-125 in units not exceeding ~~five hundredths microcurie [1.85 kilobecquerels]~~ one and eighty-five hundredths kilobecquerels [0.5 microcurie] of iodine-129 and ~~five thousandths microcurie [185 becquerels]~~ one and eighty-five hundredths kilobecquerels [0.5 microcurie] of americium-241 each.

(f) Iodine-131 in units not exceeding ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(g) Iron-59 in units not exceeding ~~twenty microcuries [740 kilobecquerels]~~ seven hundred forty kilobecquerels [20 microcuries] each.

(h) Selenium-75 in units not exceeding ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; ~~fifty microcuries [1.85~~

~~megabeequerels~~] one and eighty-five hundredths megabecquerels [50 microcuries] of hydrogen-3 (tritium); ~~twenty------microcuries------[740 kilobeequerels]~~ seven hundred forty kilobecquerels [20 microcuries] of iron-59; or mock iodine-125 in units not exceeding ~~five-hundredths-microcurie-[1.85-kilobeequerels]~~ one and eighty-five hundredths kilobecquerels [0.05 microcurie] of iodine-129 and ~~five-thousandths-microcurie-[185-beequerels]~~ one hundred eighty-five hundredths becquerels [0.005 microcurie] of americium-241 each.

(b) Displaying the radiation caution symbol described in subdivision a of subsection 1 of section 33-10-04.1-13 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

_____
Name of manufacturer

(b) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to

this article and a general license of a licensing state.

_____
Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in subsection 1 of section 33-10-04.1-14.

h. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under subdivision g of subsection 2 of section 33-10-03-04 will be approved if: (1) the applicant satisfies the general requirements of subsection 2 of this section and, (2) the criteria of 10 CFR 32.61, 32.62, and 32.103 are met.

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

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

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

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

[1] ~~The------radiopharmaceutical-----containing radioactive-material-will-be--manufactured, labeled,--and-packed-in-accordance-with-the Federal-Food,-Drug,-and-Cosmetic-Act-or-the Public--Health--Service--Act,-such-as-a-new drug-application--approved--by--the--United States--food--and--drug-administration-or-a~~

~~"Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the United States food and drug administration; or~~ Registered or licensed with the United States food and drug administration as a drug manufacturer;

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

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

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

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

(d) The applicant satisfied the following labeling requirements:

[1] ~~The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the department for distribution to persons licensed pursuant to this chapter for the uses listed in subsection 1 of section 33-10-07-06, subsection 1 of section 33-10-07-07, and subsection 1 of section 33-10-07-08, or under equivalent licenses of the United States nuclear regulatory commission, an agreement state, or a licensing state.~~ A label is affixed to each transport radiation shield whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to

be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than one hundred days, the time may be omitted.

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

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

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

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

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

[2] This individual meets the requirements specified in subsection 13 of section

33-10-07-12 and subdivision b of subsection 15 of section 33-10-07-12 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

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

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

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

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

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-emitting, beta-emitting, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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

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

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

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

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

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

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

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

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

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

~~(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:~~

~~(a) Adequate information, from a radiation safety standpoint, on the procedures to be followed and~~

the--equipment--and--shielding--to--be--used--in eluting-the-generator-or-processing--radioactive material-with-the-reagent-kit.

(b)--A--statement--that-this-generator-or-reagent-kit (as-appropriate)-is-approved-for-use-by--persons licensed---by---the---department---pursuant---to subsection-1-of--section--33-10-07-07--or--under equivalent-licenses-of-the-United-States-nuclear regulatory-commission,-an-agreement-state,-or--a licensing---state.---The--labels,--leaflets,--or brochures-required-by-this--subdivision--are--in addition--to-the-labeling-required-by-the-United States-food-and-drug-administration-and-they-may be--separate--from--or,-with-the-approval-of-the United-States-food-and-drug-administration,--may be--combined--with--the-labeling-required-by-the United-States-food-and-drug-administration.

Note:---Although--the--department--does--not--regulate-the manufacture-and-distribution-of-reagent-kits-that--do--not contain--radioactive-material,-it-does-regulate-the-use-of such----reagent----kits----for----the----preparation----of radiopharmaceuticals--containing--radioactive--material-as part-of-its-licensing--and--regulation--of--the--users--of radioactive--material.---Any--manufacturer-of-reagent-kits that-do-not-contain-radioactive-material--who--desires--to have--the--reagent-kits-approved-by-the-department-for-use by-persons-licensed-pursuant-to--subsection-1--of--section 33-10-07-07-may-submit-the-pertinent-information-specified in-this-subdivision.

k. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to chapter 33-10-07 for use as a calibration or reference source or for the uses listed in subsection 1 of section 33-10-07-09 and subsection 1 of section 33-10-07-10 will be approved if:

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

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form, and amount.

(b) Details of design and construction of the source or device.

(c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents.

(d) For devices containing radioactive material, the radiation profile of a prototype device.

(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests.

(f) Procedures and standards for calibrating sources and devices.

(g) Legend and methods for labeling sources and devices as to their radioactive content.

(h) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the department for distribution to persons licensed pursuant to chapter 33-10-07, subsection 1 of section 33-10-07-09, and subsection 1 of section 33-10-07-10, or under equivalent licenses of the United States nuclear regulatory commission, an agreement state, or a licensing state; provided, that such labeling for sources which do not require long-term storage may be on a leaflet or brochure which accompanies the source.

(4) If the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(5) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes, but is not limited to:

(a) Primary containment or source capsule.

(b) Protection of primary containment.

(c) Method of sealing containment.

(d) Containment construction materials.

(e) Form of contained radioactive material.

(f) Maximum temperature withstood during prototype tests.

(g) Maximum pressure withstood during prototype tests.

(h) Maximum quantity of contained radioactive material.

(i) Radiotoxicity of contained radioactive material.

(j) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

~~l.~~ k. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to subdivision e of subsection 1 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar year a

radiation dose in excess of ten percent of the limits specified in subsection 1 of section 33-10-04.1-06.

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the department will approve an application for a specific license under this subdivision only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The department may deny any application for a specific license under this subdivision if the end uses of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to paragraph 1 shall:

(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device.

(b) Label or mark each unit to:

[1] Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

[2] State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the United States nuclear regulatory commission or of an agreement state.

(c) Assure that the depleted uranium before being installed in each product or device has been

impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium".

(d) [1] Furnish a copy of the general license contained in subdivision e of subsection 1 of section 33-10-03-04 and a copy of Department Form SFN 16092 to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in subdivision e of subsection 1 of section 33-10-03-04; or

[2] Furnish a copy of the general license contained in the United States nuclear regulatory commission's or agreement state's regulation equivalent to subdivision e of subsection 1 of section 33-10-03-04 and a copy of the United States nuclear regulatory commission's or agreement state's certificate, or alternatively, furnish a copy of the general license contained in subdivision e of subsection 1 of section 33-10-03-04 and a copy of Department Form SFN 16092 to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the United States nuclear regulatory commission or an agreement state, with a note explaining that use of the product or device is regulated by the United States nuclear regulatory commission or an agreement state under requirements substantially the same as those in subdivision e of subsection 1 of section 33-10-03-04.

(e) Report to the department all transfers of industrial products or devices to persons for use under the general licensee in subdivision e of subsection 1 of section 33-10-03-04. Such report must identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed

person. If no transfers have been made to persons generally licensed under subdivision e of subsection 1 of section 33-10-03-04 during the reporting period, the report shall so indicate.

(f) [1] Report to the United States nuclear regulatory commission all transfers of industrial products or devices to persons for use under the United States nuclear regulatory commission general license in 10 CFR 40.25.

[2] Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subdivision for use under a general license in that state's regulations equivalent to subdivision e of subsection 1 of section 33-10-03-04.

[3] Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the department and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

[4] If no transfers have been made to United States nuclear regulatory commission licensees during the reporting period, this information shall be reported to the United States nuclear regulatory commission.

[5] If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency.

(g) Keep records showing the name, address, and point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in subdivision e of subsection 1 of section 33-10-03-04 or

equivalent regulations of the United States nuclear regulatory commission or of an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this subsection.

~~m.~~ l. Special requirements for issuance of specific licenses for source material milling. In addition to the requirements set forth in subsection 2, a specific license for source material milling will be issued if the applicant submits to the department a satisfactory application as described herein and meets the other conditions specified below:

(1) An application for a license to receive title to, receive, possess, and use source material for milling or byproduct material shall address the following:

(a) Description of the proposed project or action.

(b) Area/site characteristics including geology, topography, hydrology, and meteorology.

(c) Radiological and nonradiological impacts of the proposed project or action, including waterway and ground water impacts.

(d) Environmental effects of accidents.

(e) Long-term impacts including decommissioning, decontamination, and reclamation.

(f) Site and project alternatives.

(Note: In this paragraph, "byproduct material" means the tailings or waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.)

(2) Pursuant to subdivision f of subsection 2, the applicant may not commence construction of the project until the department has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(3) At least one full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the

construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

(4) Prior to issuance of the license, the mill operator shall establish financial surety arrangements consistent with the requirements of subdivision g of subsection 2.

(a) The amount of funds to be ensured by financial surety arrangements shall be based on department-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the department may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the department to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities

performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time, e.g., five years, which must be automatically renewed unless the surety agent notifies the beneficiary (the state regulatory agency) and the principal (the licensee) some reasonable time, e.g., ninety days, prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least sixty days for the regulatory agency to collect.

(b) The total amount of funds for reclamation or long-term surveillance and control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long-term surveillance and control. Such funds do not, however, include moneys held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.

(5) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.

(a) Milling operations shall be conducted so that all effluent releases are reduced to as low as is reasonably achievable below the limits of chapter 33-10-04.1.

(b) The mill operator shall conduct daily inspection of any tailings or waste retention systems.

Records of such inspections shall be maintained for review by the department.

(c) The mill operator shall immediately notify the department of the following:

[1] Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas.

[2] Any unusual conditions (conditions not contemplated in the design of the retention system) which if not corrected could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

(6) Continued surveillance requirements for source material mills having reclaimed residues.

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

(b) A minimum charge of two hundred fifty thousand dollars in 1978 dollars to cover the costs of long-term surveillance shall be paid by each mill operator to the department prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in subparagraph a, additional funding requirements may be specified by the department. The total charge to cover the costs

of long-term surveillance shall be such that, with an assumed one percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The charge will be reviewed annually to recognize or adjust for inflation.

(7) An application for a license to own, receive, possess, and use byproduct material as defined in section 33-10-01-04 shall contain proposed specifications relating to the emissions control and disposition of the byproduct material to achieve the requirements and objectives set forth in the criteria listed in Schedule D of chapter 33-10-03.

6. **Issuance of specific licenses.**

a. Upon a determination that an application meets the requirements of North Dakota Century Code chapter 23-20.1 and this article, the department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this chapter as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property.

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary.

(3) Prevent loss or theft of material subject to this chapter.

7. **Specific terms and conditions of licenses.**

a. Each license issued pursuant to this chapter shall be subject to all the provisions of North Dakota Century Code chapter 23-20.1, now or hereafter in effect, and to all applicable rules and orders of the department.

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of,

either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information find that the transfer is in accordance with the provisions of North Dakota Century Code chapter 23-20.1, now or hereafter in effect, and to all valid rules and orders of the department, and shall give its consent in writing.

c. Each person licensed by the department pursuant to this chapter shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

d. Licensees required to submit emergency plans under subdivision b of subsection 3 shall follow the emergency plan approved by the department. The licensee may change the ~~proved~~ approved plan without department approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the department and to affected onsite response organizations within six months after the change is made. Proposed changes that decrease or potentially decrease the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the department.

e. Each licensee shall notify the department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

f. Each licensee shall notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(14) [Pub. L. 95-598; 92 Stat. 2549]) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2) [Pub.L. 95-598; 92 Stat. 2549]) of the licensee.

This notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

8. **Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.**

a. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under subsection 9 not less than thirty days before the expiration date stated in the existing license. If an application for renewal has been filed at least thirty days prior to the expiration date stated in the existing license, the existing license shall not expire until final action is taken on the renewal application by the department, or shall expire at the end of the day on which the department makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

b. Each specific license revoked by the department expires at the end of the day on the date of the department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by department order.

c. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the department notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) Limit actions involving radioactive material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with requirements in article 33-10.

d. Within sixty days of the occurrence of any of the following, consistent with the administrative directions in section 33-10-01-13, each licensee shall provide notification to the department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with requirements in article 33-10, or submit within twelve months of notification a decommissioning plan, if required by paragraph 1 of subdivision f, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to subdivision a or b;

(2) The licensee has decided to permanently cease principal activities, as defined in section 33-10-01-04, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with requirements in article 33-10;

(3) No principal activities under the license have been conducted for a period of twenty-four months; or

(4) No principal activities have been conducted for a period of twenty-four months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with requirements in article 33-10.

e. Coincident with the notification required by subdivision d, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to subsection 14 in conjunction with a license issuance or renewal or as required by this subsection. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subparagraph e of paragraph 4 of subdivision g.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the department.

f. The department may grant a request to extend the time periods established in subdivision d if the department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than thirty days before notification pursuant to subdivision d. The schedule for decommissioning set forth in subdivision d may not commence until the department has made a determination on the request.

f.g. (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have

not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(a) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(b) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(c) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(d) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to subdivision d if the department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in paragraph 1 of subdivision ~~f~~ g with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(a) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(b) A description of planned decommissioning activities;

(c) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(d) A description of the planned final radiation survey; and

(e) An updated detailed cost estimate with present funds set aside for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(f) For decommissioning plans calling for completion of decommissioning later than twenty-four months after plan approval, the plan must include a justification for the delay based on the criteria in subdivision ~~h~~ i.

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

~~g.~~h. (1) Except as provided in subdivision ~~h~~ i, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as ~~practicable~~ practical but no later than twenty-four months following the initiation of decommissioning.

(2) Except as provided in subdivision ~~h~~ i, when decommissioning involves the entire site, the licensee shall request license termination as soon as ~~practicable~~ practical but no later than twenty-four months following the initiation of decommissioning.

~~h.~~ i. The department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the department determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted twenty-four-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted twenty-four-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground water treatment activities, monitored natural ground water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

~~i.~~ j. As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed radiation control program form 1 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in section 33-10-04.1-18 in some other manner. The licensee shall, as appropriate:

(a) Report levels of gamma radiation in units of millisieverts (millirem) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per one hundred square centimeters, removable and fixed, for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(b) Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

~~j.~~ k. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the department determines that:

(1) Radioactive material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) (a) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with ~~requirements--in article 33-10~~ the criteria for decommissioning in section 33-10-04.1-18;

(b) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with ~~requirements in article 33-10~~ the criteria for decommissioning in section 33-10-04.1-18.

(4) Records required by subsection 14 of section 33-10-03-05 and sections 33-10-04.1-14 and 33-10-04.1-15 have been received.

9. **Renewal of licenses.** Applications for renewal of specific licenses shall be filed in accordance with subsection 1.

10. **Amendment of licenses at request of licensee.** Applications for amendment of a license shall be filed in accordance with subsection 1 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

11. **Department action on applications to renew or amend.** In considering an application by a licensee to renew or amend the license, the department will apply the criteria set forth in subsection 2, 3, 4, 5, or 14, and chapters 33-10-05, 33-10-07, or 33-10-12, as applicable.

12. **Transfer of material.**

a. No licensee shall transfer radioactive material except as authorized pursuant to this subsection.

b. Except as otherwise provided in one's license and subject to the provisions of subdivisions c and d, any licensee may transfer radioactive material:

(1) To the department. (A licensee may transfer material to the department only after receiving prior approval from the department.)

(2) To the United States department of energy.

(3) To any person exempt from this article to the extent permitted under such exemption.

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States

nuclear regulatory commission, any agreement state, or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the department, an agreement state, or a licensing state.

(5) As otherwise authorized by the department in writing.

c. Before transferring radioactive material to a specific licensee of the department, the United States nuclear regulatory commission, an agreement state, or a licensing state, or to a general licensee who is required to register with the department, the United States nuclear regulatory commission, an agreement state, or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by subdivision c is acceptable:

(1) The transferor may possess and read, a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed, in writing, within ten days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the department, the United States nuclear regulatory commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in paragraphs 1 through 4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the United States nuclear regulatory commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of chapter 33-10-13.

13. **Modification and revocation of licenses.**

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to North Dakota Century Code chapter 23-20.1, or by reason of this article, and orders issued by the department.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of North Dakota Century Code chapter 23-20.1, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of North Dakota Century Code chapter 23-20.1, or of the license, or of this article, or any order of the department.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee, in writing, and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

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

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than one hundred twenty days and in quantities exceeding one hundred thousand times the applicable quantities set forth in Schedule F of this chapter shall submit a decommissioning funding plan as described in subdivision e. The decommissioning funding

plan must also be submitted when a combination of isotopes is involved if R divided by one hundred thousand is greater than one (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Schedule F of this chapter.

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

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

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by subdivision d using one of the methods described in subdivision f. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but ~~prior to~~ before the receipt of licensed material. ~~As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of subdivision f is to be submitted to the department.~~ If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of subdivision f must be submitted to the department before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall supply to the department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of subdivision f.

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

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

decommissioning funding plan ~~at--this--time~~, the licensee shall include a decommissioning funding plan in any application for license renewal.

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

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

Greater than ten thousand but less than or equal to one hundred thousand times the applicable quantities of Schedule F in unsealed form. (For a combination of isotopes, if R, as defined in subdivision a, divided by ten thousand is greater than one but R divided by one hundred thousand is less than or equal to one)	$750,000
Greater than one thousand but less than or equal to ten thousand times the applicable quantities of Schedule F in unsealed form. (For a combination of isotopes, if R, as defined in subdivision a, divided by one thousand is greater than one but R divided by ten thousand is less than or equal to one)	$150,000
Greater than ten billion times the applicable quantities of Schedule F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in subdivision a, divided by ten billion is greater than one)	$75,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from subdivision f, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided

in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of subdivision f.

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

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

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

(a) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless ninety days or more prior to the renewal date, the issuer notifies the department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the

department within thirty days after receipt of notification of cancellation.

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

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

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

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

(5) When a governmental agency is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental agency.

g. Each person licensed shall keep records of information important to the ~~safe-and-effective~~ decommissioning of ~~the~~ a facility in an identified location until the ~~license-is terminated--by--the--department~~ site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with subdivision b of subsection 7 of section 33-10-03-05, licensees shall transfer all records described in this subdivision to the new licensee. In this case, the new licensee shall

maintain these records until the license is terminated. If records ~~of--relevant--information~~ important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the department considers important to decommissioning consists of:

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

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

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

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

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

(c) All areas outside of restricted areas where current and previous wastes have been buried as documented under subsection 9 of section 33-10-04.1-15; and

(d) All areas outside of restricted areas which contain material such that, if the license

expired, the licensee would be required to either decontaminate the area to ~~unrestricted release----levels~~ meet the criteria for decommissioning in section 33-10-04.1-18 or apply for approval for disposal under subsection 2 of section 33-10-04.1-14.

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

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04, 23-20.1-04.1, 23-20.1-04.2, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.1, 23-20.1-04.2, 23-20.1-04.5

33-10-03-06. Reciprocal recognition of licenses.

1. Licenses of byproduct, source, and special nuclear material in quantities not sufficient to form a critical mass.

   a. Subject to this article, any person who holds a specific license from the United States nuclear regulatory commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state except in areas of exclusive federal jurisdiction for a period not in excess of one hundred eighty days in any calendar year provided that:

      (1) The licensing document does not limit the activity authorized by such document to specified installations or locations.

      (2) The out-of-state licensee notifies the department, in writing, at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document and a copy of the licensee's operating and procedures manual. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The

department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

(3) The out-of-state licensee complies with this article and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with this article.

(4) The out-of-state licensee supplies such other information as the department may request.

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subdivision except by transfer to a person:

(a) Specifically licensed by the department or the United States nuclear regulatory commission to receive such material; or

(b) Exempt from the requirements for a license for such material under subdivision a of subsection 2 of section 33-10-03-02.

(6) The out-of-state licensee shall submit an annual reciprocity fee, as prescribed in chapter 33-10-11, at the time of written notification.

b. Notwithstanding the provisions of subdivision a, any person who holds a specific license issued by the United States nuclear regulatory commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in paragraph 1 of subdivision b of subsection 2 of section 33-10-03-04 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state except in areas of federal jurisdiction provided that:

(1) The person shall file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device.

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the United States nuclear regulatory commission or an agreement state.

(3) The person shall ensure that any labels required to be affixed to the device under rules of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited".

(4) The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04.

(5) The out-of-state licensee shall submit an annual reciprocity fee, as prescribed in chapter 33-10-11, at the time of written notification.

c. The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the United States nuclear regulatory commission or an agreement state, or of any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

2. Licenses of naturally occurring and accelerator-produced radioactive material.

a. Subject to this article, any person who holds a specific license from a licensing state, and issued by the department having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty days in any calendar year provided that all of the following requirements are met:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations.

(2) The out-of-state licensee notifies the department, in writing, at least three days prior to engaging in such activity. Such notification must indicate the location, period, and type of proposed possession and

use within the state, and must be accompanied by a copy of the pertinent licensing document and a copy of the licensee's operating and procedures manual. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in subdivision a.

(3) The out-of-state licensee complies with this article and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with this article.

(4) The out-of-state licensee supplies such other information as the department may request.

(5) The out-of-state licensee may not transfer or dispose of radioactive material possessed or used under the general license provided in subdivision a except by transfer to a person:

(a) Specifically licensed by the department or by another licensing state to receive such material; or

(b) Exempt from the requirements for a license for such material under subsection 2 of section 33-10-03-02.

(6) The out-of-state licensee shall submit an annual reciprocity fee, as described in chapter 33-10-11, at the time of written notification.

b. Notwithstanding the provisions of subdivision a, any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in paragraph 1 of subdivision b of subsection 2 of section 33-10-03-04 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

(1) Such person shall file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or

installed in this state. Each such report must identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a licensing state;

(3) Such person shall assure that any labels required to be affixed to the device under rules of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited";

(4) The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04 or in equivalent regulations of another licensing state having jurisdiction over the manufacture and distribution of the device; and

(5) The out-of-state licensee shall submit an annual reciprocity fee, as prescribed in chapter 33-10-11, at the time of written notification.

c. The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; May 1, 1998.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.5

SCHEDULE D
CRITERIA RELATED TO THE DISPOSITION OF
URANIUM MILL TAILINGS OR WASTES

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

In many cases, flexibility is provided in the criteria to allow achieving an optimum tailings disposal program on a site specific basis. However, in such cases the objectives, technical alternatives, and concerns which must be taken into account in developing a tailings program are identified. Applications for licenses must clearly demonstrate how the criteria have been addressed.

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

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

CRITERION 1 - In selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites, the following site features, which will determine the extent to which a program meets the broad objective of isolating the tailings and associated contaminants from man and the environment during operations and for thousands of years thereafter without ongoing active maintenance, shall be considered:

- remoteness from populated areas;

- hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from useable groundwater sources; and

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

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

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

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

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

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

alternate sites are not available. Where full below-grade burial is not ~~practicable~~ practical, the size of retention structures, and size and steepness of slopes of associated exposed embankments, shall be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrogeologic conditions at a site. In these cases, it must be demonstrated that an above-grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

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

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

(b) Topographic features shall provide good wind protection.

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

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

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

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

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

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

- steepness of underlying slopes.

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

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

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

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

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

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

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

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

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

- Neutralization to promote immobilization of toxic substances.

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

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

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

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

- The chemical and radioactive characteristics of the waste solutions.

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

- This information shall be gathered by borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to usable ground water. The information gathered on boreholes shall include both geologic and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits which are of high hydraulic conductivity. If field survey methods are used, they

should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability shall not be determined on the basis of laboratory analysis of samples alone; a sufficient amount of field testing (e.g., pump tests) shall be conducted to assure actual field properties are adequately understood. Testing shall be conducted to allow estimating chemisorption attenuation properties of underlying soil and rock.

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

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

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

conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action shall be taken when performance is outside of prescribed ranges. Effluent control devices shall be operative at all times during drying and packaging operations and whenever air is exhausting from the yellowcake stack.

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

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

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

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

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

Title to the byproduct material license pursuant to subdivision m of subsection 5 of section 33-10-03-05 and land, including any interests therein (other than land owned by the United States or by a state) which is used for the disposal of any such byproduct material, or is essential to ensure the long-term stability of such disposal site, shall be transferred to the United States or the

state in which such land is located, at the option of such state. In view of the fact that physical isolation must be the primary means of long-term control, and government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests, for example, mineral rights, may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either a United States nuclear regulatory commission general or specific license prohibiting the disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the department may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or the state.

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

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

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

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998.

CHAPTER 33-10-04.1

33-10-04.1-02. Scope. This chapter applies to persons licensed or registered by the department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to ~~exposure of patients to radiation for the purpose of~~ any medical ~~diagnosis or therapy~~ administration or therapy the individual has received, to exposure from individuals administered radioactive material and released in accordance with subsection 12 of section 33-10-07-05, or to voluntary participation in medical research programs.

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

33-10-04.1-03. Definitions. As used in this chapter:

1. "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. Annual limit on intake is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of five-hundredths sievert [5 rem] or a committed dose equivalent of five-tenths sievert [50 rem] to any individual organ or tissue. Annual limit on intake values for intake by ingestion and by inhalation of selected radionuclides are given in table I, columns 1 and 2, of appendix B.

2. "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for class D, days, of less than ten days, for class W, weeks, from ten to one hundred days, and for class Y, years, of greater than one hundred days. "Lung class" and "inhalation class" are equivalent terms.

3. "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

4. "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of two thousand hours under conditions of light work, results in an intake of one annual limit on intake. The condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for two thousand hours in a

year. Derived air concentration values are given in table I, column 3, of appendix B.

5. "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take two thousand derived air concentration-hours to represent one annual limit on intake, equivalent to a committed effective dose equivalent of five-hundredths sievert [5 rem].

6. "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

7. "Inhalation class" [see "class"].

8. "Lung class" [see "class"].

9. "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. "Deterministic effect" is an equivalent term.

10. "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

11. "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately thirteen consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

12. "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man".

13. "Respiratory ~~protective~~ protection equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

14. "Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

15. "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. "Probabilistic effect" is an equivalent term.

16. "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five gray [500 rad] in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. (At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.).

17. "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole body	1.00[b]

[a] 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be

approved on a case-by-case basis until such time as specific guidance is issued.

History: Effective March 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03

33-10-04.1-05. Radiation protection programs.

1. Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See subsection 2 of section 33-10-04.1-15 for recordkeeping requirements relating to these programs.

2. To the extent practicable, the licensee or registrant shall use procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

3. At intervals not to exceed twelve months, the licensee or registrant shall review the radiation protection program content and implementation.

4. To implement the as low as is reasonably achievable (ALARA) requirements of subsection 2, and notwithstanding the requirements of subsection 1 of section 33-10-04.1-07, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of one-tenth millisieverts [10 mrem] per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in subsection 3 of section 33-10-04.1-16 and promptly take appropriate corrective action to ensure against recurrence.

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

33-10-04.1-06. Occupational dose limits.

1. **Occupational dose limits for adults.**

   a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special

exposures pursuant to subsection 6, to the following dose limits:

(1) An annual limit, which is the more limiting of:

(a) The total effective dose equivalent being equal to five-hundredths sievert [5 rem]; or

(b) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to five-tenths sievert [50 rem].

(2) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(a) An eye dose equivalent of fifteen-hundredths sievert [15 rem]; and

(b) A shallow dose equivalent of five-tenths sievert [50 rem] to the skin or to any extremity.

b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See paragraphs 1 and 2 of subdivision e of subsection 6.

c. The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

(1) The deep dose equivalent, eye dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(2) Reserved.

d. Derived air concentration and annual limit on intake values are presented in table I of appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See subsection 7 of section 33-10-04.1-15.

e. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten

milligrams in a week in consideration of chemical toxicity. See footnote 3 of appendix B.

f. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See subdivision e of subsection 5.

2. **Compliance with requirements for summation of external and internal doses.**

a. If the licensee or registrant is required to monitor pursuant to both subdivision a and subdivision b of subsection 2 of section 33-10-04.1-09, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subdivision a of subsection 2 of section 33-10-04.1-09 or only pursuant to subdivision b of subsection 2 of section 33-10-04.1-09, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subdivision b, subdivision c, and subdivision d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

b. Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation annual limit on intake for each radionuclide, or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by two thousand, or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than ten percent of the maximum weighted

value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

c. Intake by oral ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral annual limit on intake, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

d. Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of derived air concentration for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subdivision.

3. **Determination of external dose from airborne radioactive material.**

a. Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See appendix B, footnotes 1 and 2.

b. Airborne radioactivity measurements and derived air concentration values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

4. **Determination of internal exposure.**

a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to subsection 2 of section 33-10-04.1-09, take suitable and timely measurements of:

(1) Concentrations of radioactive materials in air in work areas;

(2) Quantities of radionuclides in the body;

(3) Quantities of radionuclides excreted from the body; or

(4) Combinations of these measurements.

b. Unless respiratory ~~protective~~ protection equipment is used, as provided in subsection 3 of section 33-10-04.1-11, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record;

(2) Upon prior approval of the department, adjust the derived air concentration or annual limit on intake values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(3) Separately assess the contribution of fractional intakes of class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See appendix B.

d. If the licensee or registrant chooses to assess intakes of class Y material using the measurements given in paragraph 2 or 3 of subdivision a, the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by subsection 2 or 3 of section 33-10-04.1-16. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the derived air concentration applicable to the mixture for use in calculating derived air concentration-hours shall be either:

(1) The sum of the ratios of the concentration to the appropriate derived air concentration value, that is, D, W, or Y, from appendix B for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive

derived air concentration value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the derived air concentration for the mixture shall be the most restrictive derived air concentration of any radionuclide in the mixture.

g. When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

(1) The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in subsection 1 and in complying with the monitoring requirements in subdivision b of subsection 2 of section 33-10-04.1-09, and

(2) The concentration of any radionuclide disregarded is less than ten percent of its derived air concentration, and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed thirty percent.

h. When determining the committed effective dose equivalent, the following information may be considered:

(1) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one annual limit on intake, or an exposure of two thousand derived air concentration-hours, results in a committed effective dose equivalent of five-hundredths sievert [5 rem] for radionuclides that have their annual limit on intakes or derived air concentrations based on the committed effective dose equivalent.

(2) For an annual limit on intake and the associated derived air concentration determined by the nonstochastic organ dose limit of five-tenths sievert [50 rem], the intake of radionuclides that would result in a committed effective dose equivalent of five-hundredths sievert [5 rem], that is, the stochastic annual limit on intake, is listed in parentheses in table I of appendix B. As a simplifying assumption, the licensee or registrant may use the stochastic annual limit on intake to determine committed effective dose equivalent. However, if the licensee or registrant uses the

stochastic annual limit on intake, the licensee or registrant shall also demonstrate that the limit in subparagraph 2 of paragraph 1 of subdivision a of subsection 1 is met.

5. **Determination of prior occupational dose.**

   a. For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to subsection 2 of section 33-10-04.1-09, the licensee or registrant shall:

      (1) Determine the occupational radiation dose received during the current year; and

      (2) Attempt to obtain the records of cumulative occupational radiation dose.

   b. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

      (1) The internal and external doses from all previous planned special exposures;

      (2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

      (3) All lifetime cumulative occupational radiation dose.

   c. In complying with the requirements of subdivision a, a licensee or registrant may:

      (1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;

      (2) Accept, as the record of cumulative radiation dose, an up-to-date department's occupational radiation exposure history form (SFN 19443) or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

      (3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving

radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

d. (1) The licensee or registrant shall record the exposure history, as required by subdivision a, on the department's occupational radiation exposure history form (SFN 19443), or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the department's occupational radiation exposure history form (SFN 19443) or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the department's occupational radiation exposure history form (SFN 19443) or equivalent indicating the periods of time for which data are not available.

(2) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in chapter 33-10-04 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on the department's occupational radiation exposure history form (SFN 19443) or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

e. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(1) In establishing administrative controls pursuant to subdivision f of subsection 1 for the current year, that the allowable dose limit for the individual is reduced by twelve and five-tenths millisieverts [1.25 rem] for each quarter for which records were unavailable and the individual was engaged in

activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

f. The licensee or registrant shall retain the records on the department's occupational radiation exposure history form (SFN 19443) or equivalent until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the department's occupational radiation exposure history form (SFN 19443) or equivalent for three years after the record is made.

6. **Planned special exposures.** A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subsection 1 provided that each of the following conditions is satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

b. The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

c. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose as low as reasonably achievable considering other risks that may be present.

d. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by subdivision b of subsection 5 during the lifetime of the individual for each individual involved.

e. Subject to subdivision b of subsection 1, the licensee or registrant shall not authorize a planned special exposure

that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(1) The numerical values of any of the dose limits in subdivision a of subsection 1 in any year; and

(2) Five times the annual dose limits in subdivision a of subsection 1 during the individual's lifetime.

f. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with subsection 6 of section 33-10-04.1-15 and submits a written report in accordance with subsection 4 of section 33-10-04.1-16.

g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within thirty days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to subdivision a of subsection 1 but shall be included in evaluations required by subdivisions d and e.

7. **Occupational dose limits for minors.** The annual occupational dose limits for minors are ten percent of the annual occupational dose limits specified for adult workers in subsection 1.

8. **Dose to an embryo or fetus.**

a. The licensee or registrant shall ensure that the dose to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five millisievert [0.5 rem]. See subsection 7 of section 33-10-04.1-15 for recordkeeping requirements.

b. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in subdivision a (the national council on radiation protection and measurements recommended in NCRP report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than five-tenths millisievert [0.05 rem] to the embryo or fetus be received in any one month).

c. The dose to an embryo or fetus shall be taken as the sum of:

(1) The deep dose equivalent to the declared pregnant woman; and

(2) The dose to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.

d. If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo or fetus has exceeded four and five-tenths millisievert [0.45 rem], the licensee or registrant shall be deemed to be in compliance with subdivision a of subsection 8 of section 33-10-04.1-06 if the additional dose to the embryo or fetus does not exceed five-tenths millisievert [0.05 rem] during the remainder of the pregnancy.

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

33-10-04.1-07. Radiation dose limits for individual members of the public.

1. **Dose limits for individual members of the public.**

a. Each licensee or registrant shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one millisievert [0.1 rem] in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with subsection 12 of section 33-10-07-05, voluntary participation in medical research programs, and the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with subsection 3 of section 33-10-04.1-14. Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994, and met the previous requirements of five millisievert [0.5 rem] in a year; and

(2) The dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in accordance with subsection 12 of section

33-10-07-05 does not exceed two-hundredths millisievert [0.002 rem] in any one hour.

b. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

c. A licensee, registrant, or an applicant for a license or registration may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of five millisievert [0.5 rem]. This application shall include the following information:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in subdivision a;

(2) The licensee's or registrant's program to assess and control dose within the five millisievert [0.5 rem] annual limit; and

(3) The procedures to be followed to maintain the dose as low as reasonably achievable.

d. In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of the United States environmental protection agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

e. The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

2. **Compliance with dose limits for individual members of the public.**

a. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in subsection 1.

b. A licensee or registrant shall show compliance with the annual dose limit in subsection 1 by:

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed

or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

(a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table II of appendix B; and

(b) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed two-hundredths millisievert [0.002 rem] in an hour and five-tenths millisievert [0.05 rem] in a year.

c. Upon approval from the department, the licensee or registrant may adjust the effluent concentration values in appendix B, table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

History: Effective March 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-11. Respiratory protection and controls to restrict internal exposure in restricted areas.

1. **Use of process or other engineering controls.** The licensee or registrant shall use, to the extent ~~practicable~~ practical, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.

2. **Use of other controls.** When it is not ~~practicable~~ practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant, consistent with maintaining the total effective dose equivalent as low as is reasonably achievable (ALARA), shall increase monitoring and limit intakes by one or more of the following means:

a. Control of access;

b. Limitation of exposure times;

c. Use of respiratory protection equipment; or

d. Other controls.

3. **Use of individual respiratory protection equipment.**

a. If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to subsection 2:

(1) Except as provided in paragraph 2, the licensee or registrant shall use only respiratory protection equipment that is tested and certified or had certification extended by the national institute for occupational safety and health and the mine safety and health administration.

(2) The licensee or registrant may use respiratory protection equipment that has not been tested or certified by the national institute for occupational safety and health and the mine safety and health administration, has not had certification extended by the national institute for occupational safety and health and the mine safety and health administration, or for which there is no schedule for testing or certification, provided the licensee or registrant has submitted to the department and the department has approved an application for authorized use of that respiratory protection equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the respiratory protection equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(3) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(a) Air sampling sufficient to identify the potential hazard, permit proper respiratory protection equipment selection, and estimate exposures;

(b) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(c) Testing of ~~respirators~~ respiratory protection equipment for operability immediately prior to each use;

(d) Written procedures regarding selection, fitting, issuance, maintenance, and testing of ~~respirators~~ respiratory protection equipment, including testing for operability immediately

prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(e) Determination by a physician prior to initial fitting of ~~respirators~~ respiratory protection equipment, and ~~at--least~~ either every twelve months thereafter or periodically at a frequency determined by a physician, that the individual user is ~~physically-able~~ medically fit to use the respiratory protection equipment.

(4) The licensee or registrant shall issue a written policy statement on ~~respirator~~ respiratory protection equipment usage covering:

(a) The use of process or other engineering controls, instead of ~~respirators~~ respiratory protection equipment;

(b) The routine, nonroutine, and emergency use of ~~respirators~~ respiratory protection equipment; and

(c) The length of periods of ~~respirator~~ respiratory protection equipment use and relief from ~~respirator~~ respiratory protection equipment use.

(5) The licensee or registrant shall advise each ~~respirator~~ respiratory protection equipment user that the user may leave the area at any time for relief from ~~respirator~~ respiratory protection equipment use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(6) The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

b. When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to subsection 2, provided that the following conditions, in addition to those in subdivision a, are satisfied:

(1) The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in appendix B, table I, column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the ~~peak-concentration~~ multiple defined in the preceding sentence is inconsistent with the goal specified in subsection 2 of keeping the total effective dose equivalent as low as is reasonably achievable, the licensee or registrant may select respiratory protection equipment with a lower protection factor ~~provided that~~ only if such a selection would result in a keeping the total effective dose equivalent ~~that is~~ as low as is reasonably achievable. The concentration of radioactive material in the air that is inhaled when ~~respirators~~ respiratory protection equipment are is worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; however, if the exposure is later found to be less than initially estimated, the corrected value may be used.

(2) The licensee or registrant shall obtain authorization from the department before assigning respiratory protection factors in excess of those specified in appendix A. The department may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

(a) Describes the situation for which a need exists for higher protection factors; and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

c. In an emergency, the licensee or registrant shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the national institute for occupational safety and health and the mine safety and health administration.

d. The licensee or registrant shall notify the department in writing at least ~~twenty~~ thirty days before the date that

respiratory protection equipment is first used pursuant to either subdivision a or ~~subdivision~~ b.

4. Further restrictions on the use of respiratory protection equipment. The department may impose restrictions in addition to those in subsection 2, subsection 3, and appendix A to:

   a. Ensure that the respiratory protection program of the licensee or registrant is adequate to limit exposures of individuals to airborne radioactive materials; and

   b. Limit the extent to which a licensee may use respiratory protection equipment instead of process controls or other engineering controls.

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

33-10-04.1-13. Precautionary procedures.

1. **Caution signs.**

   a. Standard radiation symbol. Unless otherwise authorized by the department, the symbol prescribed by this subsection shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design ~~as follows:~~ as shown in appendix H.

~~RADIATION SYMBOL~~

~~(1) Cross-hatched area is to be magenta, or purple, or black, and~~

~~(2) The background is to be yellow.~~

Note: The symbol previously shown here has been removed.

   b. Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of subdivision a, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

   c. Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of

potential radiation exposures and to minimize the exposures.

2. **Posting requirements.**

a. Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

b. Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

c. Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

d. Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

e. Posting of areas or rooms in which licensed or registered material is used or stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

3. **Exceptions to posting requirements.**

a. A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

(2) The area or room is subject to the licensee's or registrant's control.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to subsection 2 provided that the patient could be released from ~~confinement~~ control pursuant to ~~chapter~~ 33-~~10~~-07 subsection 12 of section 33-10-07-05.

c. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at thirty centimeters from the surface of the sealed source container or housing does not exceed five hundredths millisievert [0.005 rem] per hour.

d. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

4. **Labeling containers and radiation machines.**

a. The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

b. Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

c. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

5. **Exemptions to labeling requirements.** A licensee or registrant is not required to label:

a. Containers holding licensed or registered material in quantities less than the quantities listed in appendix C;

b. Containers holding licensed or registered material in concentrations less than those specified in table III of appendix B;

c. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter;

d. Containers when they are in transport and packaged and labeled in accordance with the rules of the United States department of transportation (Labeling of packages containing radioactive materials is required by the United States department of transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by United States department of transportation rules 49 CFR 173.403(m) and (w) and 173.421-424.);

e. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

f. Installed manufacturing or process equipment, such as piping and tanks.

6. **Procedures for receiving and opening packages.**

a. Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a type A quantity, as defined in section 33-10-13-02 and appendix A of chapter 33-10-13, shall make arrangements to receive:

(1) The package when the carrier offers it for delivery; or

(2) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

b. Each licensee or registrant shall:

(1) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in section 33-10-01-04. Labeled package means posted with a radioactive white I, yellow II, or yellow III label as specified in United States department of transportation rules 49 CFR 172.403 and 172.436-440;

(2) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the type A quantity, as defined in section 33-10-13-02 and appendix A of chapter 33-10-13. Labeled package means posted with a radioactive white I, yellow II, or yellow III label as specified in United States department of transportation rules 49 CFR 172.403 and 172.436-440; and

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

c. The licensee or registrant shall perform the monitoring required by subdivision b as soon as ~~practicable~~ practical after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

d. The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the department when:

(1) Removable radioactive surface contamination exceeds the limits of subsection 8 of section 33-10-13-15; or

(2) External radiation levels exceed the limits of subsections 9 and 10 of section 33-10-13-15.

e. Each licensee or registrant shall:

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

f. Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a worksite are exempt from the

contamination monitoring requirements of subdivision b, but are not exempt from the monitoring requirement in subdivision b for measuring radiation levels that ensures that the source is still properly lodged in its shield.

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

33-10-04.1-14. Waste disposal.

1. **General requirements.**

   a. A licensee or registrant shall dispose of licensed or registered material only:

      (1) By transfer to an authorized recipient as provided in subsection 6 or in chapter 33-10-03, or to the United States department of energy;

      (2) By decay in storage;

      (3) By release in effluents within the limits in subsection 1 of section 33-10-04.1-07; or

      (4) As authorized pursuant to subsection 2, 3, 4, or 5.

   b. A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

      (1) Treatment prior to disposal;

      (2) Treatment or disposal by incineration;

      (3) Decay in storage;

      (4) Disposal at a land disposal facility licensed pursuant to 10 CFR 61; or

      (5) Storage until transferred to a storage or disposal facility authorized to receive the waste.

2. **Method for obtaining approval of proposed disposal procedures.** A licensee or registrant or applicant for a license or registration may apply to the department for approval of proposed procedures, not otherwise authorized in this article, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

a. A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal;

b. An analysis and evaluation of pertinent information on the nature of the environment;

c. The nature and location of other potentially affected facilities; and

d. Analyses and procedures to ensure that doses are maintained as low as is reasonably achievable and within the dose limits in this chapter.

3. **Disposal by release into sanitary sewerage.**

a. A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble, or is readily dispersible biological material, in water;

(2) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in table III of appendix B;

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(a) The licensee or registrant shall determine the fraction of the limit in table III of appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in table III of appendix B; and

(b) The sum of the fractions for each radionuclide required by subparagraph a does not exceed unity; and

(4) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed one hundred eighty-five gigabecquerels [5 Ci] of hydrogen-3, thirty-seven gigabecquerels [1 Ci]

of carbon-14, and 37 gigabecquerels [1 Ci] of all other radioactive materials combined.

b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in subdivision a.

4. **Treatment or disposal by incineration.** A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the form and concentration specified in subsection 5 or as specifically approved by the department pursuant to subsection 2.

5. **Disposal of specific wastes.**

a. A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

(1) One and eighty-five one-hundredths kilobecquerels [0.05 μCi], or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) One and eighty-five one-hundredths kilobecquerels [0.05 μCi], or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

b. A licensee or registrant shall not dispose of tissue pursuant to paragraph 2 of subdivision a in a manner that would permit its use either as food for humans or as animal feed.

c. The licensee or registrant shall maintain records in accordance with subsection 9 of section 33-10-04.1-15.

6. **Transfer for disposal and manifests.**

a. The requirements of this subsection and appendix D and appendix G are designed to control transfers of low-level radioactive waste ~~intended--for-disposal-at~~ by any waste generator, waste collector, or waste processor licensee, as defined in appendix G, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

b. Beginning March 1, 1998, all affected licensees must use appendix G. Prior to March 1, 1998, a low-level radioactive waste disposal facility operator or its

regulatory authority may require the shipper to use appendix D or appendix G. Licensees using appendix D shall comply with paragraph 1 of subdivision b of this subsection. Licensees using appendix G shall comply with paragraph 2 of subdivision b.

(1) Each shipment of radioactive waste ~~designated~~ intended for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in section I of appendix D.

(2) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the uniform low-level radioactive waste manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G.

c. Each shipment manifest shall include a certification by the waste generator as specified in section II of appendix D or appendix G, as appropriate.

d. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of appendix D or appendix G, as appropriate.

7. **Compliance with environmental and health protection rules.** Nothing in subsection 1, 2, 3, 4, 5, or 6 relieves the licensee or registrant from complying with other applicable federal, state, and local rules governing any other toxic or hazardous properties of materials that may be disposed of in accordance with subsection 1, 2, 3, 4, 5, or 6.

History: Effective March 1, 1994; amended effective July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04.1

33-10-04.1-15. Records.

1. **General provisions.**

a. Each licensee or registrant shall use the international system units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

b. Notwithstanding the requirements of subdivision a, when recording information on shipment manifests, as required in paragraph 2 of subdivision b of subsection 6 of section 33-10-04.1-14, information must be recorded in the international system of units or in the international system of units and units as specified in subdivision a.

c. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

2. **Records of radiation protection programs.**

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by paragraph 1 of subdivision a until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by paragraph 2 of subdivision a for three years after the record is made.

3. **Records of surveys.**

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by subsection 1 of section 33-10-04.1-09 and subdivision b of subsection 6 of section 33-10-04.1-13. The licensee or registrant shall retain these records for three years after the record is made.

b. The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:

(1) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) Records of the results of measurements and calculations used to determine individual intakes of

radioactive material and used in the assessment of internal dose;

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to subparagraphs a and b of paragraph 3 of subdivision a of subsection 3 of section 33-10-04.1-11; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to March 1, 1994.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

4. **Records of tests for leakage or contamination of sealed sources.** Records of tests for leakage or contamination of sealed sources (required by subsection 1 of section 33-10-04.1-08) shall be kept in units of becquerel or microcurie and maintained for inspection by the department for five years after the records are made.

5. **Records of prior occupational dose.**

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in subsection 5 of section 33-10-04.1-06 on the department's occupational radiation exposure history form (SFN 19443) or equivalent until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the department's occupational radiation exposure history form (SFN 19443) or equivalent for three years after the record is made.

b. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

6. **Records of planned special exposures.**

a. For each use of the provisions of subsection 6 of section 33-10-04.1-06 for planned special exposures, the licensee or registrant shall maintain records that describe:

(1) The exceptional circumstances requiring the use of a planned special exposure;

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(3) What actions were necessary;

(4) Why the actions were necessary;

(5) What precautions were taken to assure that doses were maintained as low as is reasonably achievable;

(6) What individual and collective doses were expected to result; and

(7) The doses actually received in the planned special exposure.

b. The licensee or registrant shall retain the records until the department terminates each pertinent license or registration requiring these records.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

7. **Records of individual monitoring results.**

a. Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to subsection 2 of section 33-10-04.1-09, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

(1) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(2) The estimated intake of radionuclides, see subsection 2 of section 33-10-04.1-06;

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to calculate the committed effective dose equivalent pursuant to subdivision c of subsection 4 of section 33-10-04.1-06;

(5) The total effective dose equivalent when required by subsection 2 of section 33-10-04.1-06; and

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

b. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in subdivision a at intervals not to exceed one year.

c. Recordkeeping format. The licensee or registrant shall maintain the records specified in subdivision a on the department's current occupational radiation exposure form (SFN 8416), in accordance with the instructions for the department's current occupational radiation exposure form (SFN 8416), or in clear and legible records containing all the information required by the department's current occupational radiation exposure form (SFN 8416).

d. The licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

e. The licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

f. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

8. **Records of dose to individual members of the public.**

a. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See subsection 1 of section 33-10-04.1-07.

b. The licensee or registrant shall retain the records required by subdivision a until the department terminates each pertinent license or registration requiring the record.

9. **Records of waste disposal.**

a. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to subsection 2, 3, 4, or 5 of section 33-10-04.1-14, chapter 33-10-03, or disposal by burial in soil, including burials authorized before October 1, 1982.

b. The licensee or registrant shall retain the records required by subdivision a until the department terminates each pertinent license or registration requiring the record.

Requirements for disposition of these records, prior to license termination, are located in subsection 14 of section 33-10-03-05 and in sections 33-10-04.1-14 and 33-10-04.1-15 for activities licensed or registered under this article.

10. **Records of testing entry control devices for very high radiation areas.**

a. Each licensee or registrant shall maintain records of tests made pursuant to paragraph 9 of subdivision b of subsection 3 of section 33-10-04.1-10 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records required by subdivision a for three years after the record is made.

11. **Form of records.** Each record required by this chapter shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or 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, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

12. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than one hundred twenty days, in an unsealed form, shall forward the following records to the department:

    a. Records of disposal of licensed material made under subsection 2 of section 33-10-04.1-14 (including records of burials made before the effective date of this section), subsections 3, 4, and 5 of section 33-10-04.1-14; and

    b. Records required by paragraph 4 of subdivision b of subsection 3 of section 33-10-04.1-15.

13. If licensed activities are transferred or assigned in accordance with subdivision b of subsection 7 of section 33-10-03-05, each licensee authorized to possess radioactive material, with a half-life greater than one hundred twenty days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the licensee is terminated:

    a. Records of disposal of licensed material made under subsection 2 of section 33-10-04.1-14 (including records of burials made before the effective date of this section), subsections 3, 4, and 5 of section 33-10-04.1-14; and

    b. Records required by paragraph 4 of subdivision b of subsection 3 of section 33-10-04.1-15.

14. Prior to license termination, each licensee shall forward the records required by subdivision g of subsection 14 of section 33-10-03-05 to the department.

History: Effective March 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-09.1

33-10-04.1-16. Reports.

1. **Reports of stolen, lost, or missing licensed or registered sources of radiation.**

    a. Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

        (1) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than one

thousand times the quantity specified in appendix C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

(2) Within thirty days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in appendix C that is still missing.

(3) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

b. Written reports. Each licensee or registrant required to make a report pursuant to subdivision a, within thirty days after making the telephone report, shall make a written report to the department setting forth the following information:

(1) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(5) Actions that have been taken, or will be taken, to recover the source of radiation; and

(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

c. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within thirty days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the department pursuant to this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

2. **Notification of incidents.**

a. Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:

(a) A total effective dose equivalent of twenty-five one-hundredths sievert [25 rem] or more;

(b) An eye dose equivalent of seventy-five one-hundredths sievert [75 rem] or more; or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of two and five-tenths gray [250 rad] or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four hours, the individual could have received an intake five times the annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

b. Twenty-four-hour notification. Each licensee or registrant, within twenty-four hours of discovery of the event, shall report to the department each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of twenty-four hours:

(a) A total effective dose equivalent exceeding five-hundredths sievert [5 rem];

(b) An eye dose equivalent exceeding fifteen-hundredths sievert [15 rem]; or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding five-tenths sievert [50 rem]; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four hours, the individual could have received an intake in excess of one annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. The licensee or registrant shall prepare each report filed with the department pursuant to this subsection so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

d. Licensees or registrants shall make the reports required by subdivisions a and b to the department by telephone, telegram, mailgram, or facsimile to the department.

e. The provisions of this subsection do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to subsection 4.

3. **Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.**

a. Reportable events. In addition to the notification required by subsection 2, each licensee or registrant shall submit a written report within thirty days after learning of any of the following occurrences:

(1) Incidents for which notification is required by subsection 2; or

(2) Doses in excess of any of the following:

(a) The occupational dose limits for adults in subsection 1 of section 33-10-04.1-06;

(b) The occupational dose limits for a minor in subsection 7 of section 33-10-04.1-06;

(c) The limits for an embryo or fetus of a declared pregnant woman in subsection 8 of section 33-10-04.1-06;

(d) The limits for an individual member of the public in subsection 1 of section 33-10-04.1-07; or

(e) Any applicable limit in the license or registration; or

(f) The as low as is reasonably achievable (ALARA) constraints for air emissions established under subsection 2 of section 33-10-04.1-05.

(3) Levels of radiation or concentrations of radioactive material in:

(a) A restricted area in excess of applicable limits in the license or registration; or

(b) An unrestricted area in excess of ten times the applicable limit set forth in this chapter or in the license or registration, whether or not involving exposure of any individual in excess of the limits in subsection 1 of section 33-10-04.1-07; or

(4) For licensees subject to the provisions of United States environmental protection agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

b. Contents of reports.

(1) Each report required by subdivision a shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) Estimates of each individual's dose;

(b) The levels of radiation and concentrations of radioactive material involved;

(c) The cause of the elevated exposures, dose rates, or concentrations; and

(d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, as low as is reasonably achievable (ALARA) constraints, generally applicable environmental standards, and associated license or registration conditions.

(2) Each report filed pursuant to subdivision a shall include for each occupationally overexposed individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in subsection 8 of section 33-10-04.1-06, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

c. All licensees or registrants who make reports pursuant to subdivision a shall submit the report in writing to the department.

4. **Reports of planned special exposures.** The licensee or registrant shall submit a written report to the department within thirty days following any planned special exposure conducted in accordance with subsection 6 of section 33-10-04.1-06, informing the department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection 6 of section 33-10-04.1-15.

5. **Reporting requirements.**

a. Immediate report. Each licensee shall notify the department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four-hour report. Each licensee shall notify the department within twenty-four hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(a) Requires access to the contaminated area, by workers or the public, to be restricted for more than twenty-four hours by imposing additional radiological controls or by prohibiting entry into the area;

(b) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of this chapter for the material; and

(c) Has access to the area restricted for a reason other than to allow isotopes with a half-life of

less than twenty-four hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(a) The equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(b) The equipment is required to be available and operable when it is disabled or fails to function; and

(c) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(a) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of this chapter for the material; and

(b) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by subdivisions a and b by telephone to the department. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(a) The caller's name and callback telephone number;

(b) A description of the event, including date and time;

(c) The exact location of the event;

(d) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(e) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by subdivisions a and b shall submit a written followup report within thirty days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

(a) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(b) The exact location of the event;

(c) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(d) Date and time of the event;

(e) Corrective actions taken or planned and the results of any evaluations or assessments; and

(f) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

6. **Reports of individual monitoring.**

a. This section applies to each person licensed or registered by the department to:

(1) Possess or use sources of radiation for purposes of industrial radiography pursuant to chapters 33-10-03 and 33-10-05;

(2) Receive radioactive waste from other persons for disposal pursuant to chapter 33-10-03; or

(3) Possess or use at any time, for processing or manufacturing for distribution pursuant to chapter 33-10-03 or 33-10-07, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

[a] The department may require as a license condition, or by rule, or order pursuant to section 33-10-01-09, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

b. Each licensee or registrant in a category listed in subdivision a shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by subsection 2 of section 33-10-04.1-09 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use the department's current occupational radiation exposure form (SFN 8416) or equivalent or electronic media containing all the information required by the department's current occupational radiation exposure form (SFN 8416).

c. The licensee or registrant shall file the report required by subdivision b, covering the preceding year, on or before April thirtieth of each year. The licensee or registrant shall submit the report to the department.

7. **Notifications and reports to individuals.**

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in subsection 3 of section 33-10-10-02.

b. When a licensee or registrant is required pursuant to ~~subsection 3~~ this section to report to the department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also ~~notify~~ provide the individual a copy of the report submitted to the department. Such ~~notice~~ reports shall be transmitted at a time not later than the transmittal to the department~~;--and--shall--comply--with--the--provisions--of subdivision-a-of-subsection-3-of-section-33-10-10-02~~.

8. **Reports of leaking or contaminated sealed sources.** The licensee or registrant shall file a report within five days with the department if the test for leakage or contamination required pursuant to subsection 1 of section 33-10-04.1-08 indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results, and the corrective action taken.

History: Effective March 1, 1994; amended effective July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-09.1

33-10-04.1-17. Additional requirements - Vacating premises. Each specific licensee or registrant shall, no less than thirty days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the department in writing of intent to vacate. When deemed necessary by the department, the licensee shall decontaminate the premises in accordance with the following or in such other manner as the department may specify.

1. **Premises.** Each licensee before vacating any premises, or transferring the premises shall permanently decontaminate such premises ~~below or equal to the standards specified in appendix F~~ to meet the criteria for decommissioning in section 33-10-04.1-18. A survey shall be made after such decontamination and the department and the landlord or subsequent tenant or transferee shall be provided with a copy of such survey no less than thirty days before vacating or relinquishing possession or control of premises. No such premises may be vacated, sold, or transferred until the decontamination survey has been verified and accepted by the department.

2. **Equipment.** No machinery, instruments, laboratory equipment, or any other property used in contact with, or close proximity to radioactive material at a licensed premises may be assigned, sold, leased, or transferred to an unlicensed person unless such property has been permanently decontaminated below or equal to the standards specified in appendix F. A survey shall be made after such decontamination and the department and subsequent transferee or owner shall be provided with a copy of such survey. No such equipment may be assigned, sold, leased, or transferred until such documentation survey has been verified and accepted by the department.

History: Effective March 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.1

33-10-04.1-18. Radiological criteria for decommissioning.

1. General provisions

a. The criteria in this section apply to the decommissioning of licensed facilities.

b. The criteria in this section do not apply to sites which:

(1) Have been decommissioned prior to January 1, 1997, and met the criteria identified in the United States nuclear regulatory commission's action plan to ensure timely cleanup of site decommissioning management plan sites in 57 FR 13389; April 16, 1992;

(2) Have previously submitted and received department approval on a decommissioning plan that is compatible with the criteria identified in the United States nuclear regulatory commission's action plan to ensure timely cleanup of site decommissioning management plan sites in 57 FR 13389; April 16, 1992; or

(3) Submit a sufficient license termination plan or decommissioning plan before January 1, 1999, and such license termination plan or decommissioning plan is approved by the department before January 1, 2000, and in accordance with the criteria identified in the United States nuclear regulatory commission's action plan to ensure timely cleanup of site decommissioning management plan sites in 57 FR 13389; April 16, 1992. If an environmental impact statement is required in the submittal, and if, because of the environmental impact statement, the department cannot approve the plan before January 1, 2000, then the department may grant an extension.

c. After a site has been decommissioned and the license terminated in accordance with the criteria in this section, the department will require additional cleanup only if, based on new information, it determines that the criteria of this section were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

d. When calculating total effective dose equivalent to the average member of the critical group the licensee shall base estimates on the greatest annual total effective dose equivalent dose expected within the first one thousand years after decommissioning. Estimates must be substantiated using actual measurements to the maximum extent practical.

2. Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent to an average member of the critical group that does not exceed twenty-five hundredths millisievert [25 millirem] per year, including that from ground water sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable. Determination of the levels which are as low as reasonably achievable shall take into account consideration of any detriments, such as loss from transportation accidents, expected to potentially result from decontamination and waste disposal.

3. Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

   a. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of subsection 2 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are as low as reasonably achievable. Determination of the levels which are as low as reasonably achievable shall take into account consideration of any detriments, such as loss from transportation accidents, expected to potentially result from decontamination and waste disposal;

   b. The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed twenty-five hundredths millisievert [25 millirem] per year;

   c. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

      (1) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in chapter 33-10-03;

      (2) Surety method, insurance, or other guarantee method as described in chapter 33-10-03;

(3) A statement of intent in the case of federal, state, or local government licensees, as described in chapter 33-10-03; or

(4) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity;

d. The licensee has submitted a decommissioning plan or license termination plan to the department indicating the licensee's intent to decommission in accordance with chapter 33-10-03, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(1) Whether provisions for institutional controls proposed by the licensee;

(a) Will provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed twenty-five hundredths millisievert [25 millirem] total effective dose equivalent per year;

(b) Will be enforceable; and

(c) Will not impose undue burdens on the local community or other affected parties;

(2) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(3) In seeking advice on the issues identified in this subdivision, the licensee shall provide for:

(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

e. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) One millisievert [100 millirem] per year; or

(2) Five millisieverts [500 millirem] per year provided the licensee:

(a) Demonstrates that further reductions in residual radioactivity necessary to comply with the one millisievert [100 millirem] per year value of paragraph 1 are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(b) Makes provisions for durable institutional controls; and

(c) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of subdivision b and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in subdivision c.

4. Alternate criteria for license termination. The department may terminate a license using alternate criteria greater than the dose criterion of subsection 2, subdivision b of subsection 3, or paragraph 1 of subdivision d of subsection 3, if the licensee:

a. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the total dose from all manmade sources combined, other than medical, would be more than the one millisievert [100 millirem per year] limit of section 33-10-04.1-07 would be unlikely, by submitting an analysis of possible sources of exposure;

b. Has employed to the extent practical restrictions on site use according to the provisions of subsection 3 in minimizing exposures at the site;

c. Reduced doses to as low as is reasonably achievable levels. Determination of the levels which are as low as reasonably achievable shall take into account consideration of any detriments, such as loss from transportation accidents, expected to potentially result from decontamination and waste disposal;

d. Has submitted a decommissioning plan or license termination plan to the department indicating the licensee's intent to decommission in accordance with subsection 8 of section 33-10-03-05 and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or the license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

   (1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

   (2) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

   (3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

e. The use of alternate criteria to terminate a license requires the approval of the department after addressing any comments provided by the United States environmental protection agency, the United States nuclear regulatory commission, and any public comments submitted pursuant to subsection 5.

5. Public notification and public participation. Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to subsection 3 or 4, or whenever the department deems such notice to be in the public interest, the department shall provide opportunity for public comment. Public comment procedures shall include the following:

   a. Notice shall be given by publication in a newspaper of general circulation in the area where the license is located or in a state publication designed to give 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 of the affected public. Notice shall be made to the United States environmental protection agency for cases where the licensee proposes to release a site pursuant to subsection 4;

   b. The notice shall identify the affected facility; the name and address of the licensee; the name and address of the department; a brief description of the plan; the name, address, and telephone number of a person from whom interested persons may obtain additional information, including copies of the plan, all relevant supporting materials, and all other materials available to the department that are relevant to the 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;

   c. 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

   d. The department shall keep a record of the commenters and also of the issues raised during the public participation process. These record shall be available to the public.

6. Minimization of contamination. Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of radioactive waste.

History: Effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.1

APPENDIX A
PROTECTION FACTORS FOR RESPIRATORS[1]

Description	Modes[3]	Protection Factors[4] Particulates only	Particulates, gases & vapors	Tested & Certified Equipment National Institute for Occupational Safety and Health & Mine Safety and Health Administration tests for permissibility
(1) AIR-PURIFYING RESPIRATORS[6]				
Facepiece, half-mask[7]	NP	10		30 CFR 11, Subpart K.
Facepiece, full	NP	50		
Facepiece, half-mask full, or hood	PP	1000		
(2) ATMOSPHERE-SUPPLYING RESPIRATORS				
1. Air-line respirator				
Facepiece, half-mask	CF		1000	
Facepiece, half-mask	D		5	
Facepiece, full	CF		2000	
Facepiece, full	D		5	30 CFR 11, Subpart J.
Facepiece, full	PD		2000[8]	
Hood	CF		[9,10]	
Suit	CF			
2. Self-contained breathing apparatus (SCBA)				
	D		50	
Facepiece, full	PD		10,000[11]	30 CFR 11, Subpart H.
Facepiece, full	RD		50	
Facepiece, full	RP		5,000[12]	
Facepiece, full				

(3)	COMBINATION RESPIRATORS Any combination of air-purifying and atmosphere-supplying respirators	Protection factor for type and mode of operation as listed above.	30 CFR 11, Sec. 11.63(b).

FOOTNOTES

1. For use in the selection of respiratory ~~protective~~ protection equipment to be used only where the contaminants have been identified and the concentrations, or possible concentrations, are known.

2. Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin. Hoods and suits are excepted.

3. The mode symbols are defined as follows:
   CF = continuous flow
   D = demand
   NP = negative pressure, that is, negative phase during inhalation
   PD = pressure demand, that is, always positive pressure
   PP = positive pressure
   RD = demand, recirculating or closed circuit
   RP = pressure demand, recirculating or closed circuit

4. a. The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory ~~protective~~ protection equipment to that inside the equipment, usually inside the facepiece, under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula: The ~~c~~concentration

inhaled = is the ~~A~~ambient airborne concentration divided by the ~~P~~protection factor.

b. The protection factors apply:

(1) Only for individuals trained in using respirators and wearing properly fitted respirators that are used and maintained under supervision in a well-planned respiratory ~~protective~~ protection program.

(2) For air-purifying respirators only when high efficiency particulate filters, above ninety-nine and ninety-seven hundredths percent removal efficiency by thermally generated three-tenths micron dioctyl phthalate (DOP) test or equivalent, are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.

(3) No adjustment is to be made for the use of sorbents against radioactive material in the form of gases or vapors.

(4) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with the national institute for occupational safety and health and the mine safety and health administration certification described in 30 CFR 11. Oxygen and air shall not be used in the same apparatus.

5. Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of less than two is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the protection factor for respiratory ~~protective~~ protection equipment is five, the effective protection factor for tritium is about one and four tenths; with protection factors of ten, the effective factor for tritium oxide is about one and seven tenths; and with protection factors of one hundred or more, the effective factor for tritium

oxide is about one and nine tenths. Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote 9 concerning supplied-air suits.

6. Canisters and cartridges shall not be used beyond service-life limitations.

7. Under-chin type only. This type of respirator is not satisfactory for use where it might be possible, such as, if an accident or emergency were to occur, for the ambient airborne concentrations to reach instantaneous values greater than 10 times the pertinent values in table I, column 3 of appendix B of chapter 33-10-04.1.1. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask is to be tested for fit prior to use, each time it is donned.

8. a. Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than one thousand may be utilized for tested-and-certified supplied-air hoods when a minimum air flow of six cubic feet per minute (0.17 m^3/min) is maintained and calibrated air line pressure gauges or flow measuring devices are used. A protection factor of up to two thousand may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than six cubic feet per minute (0.17 m^3/min) and calibrated air line pressure gauges or flow measuring devices are used.

   b. The design of the supplied-air hood or helmet, with a minimum flow of six cubic feet per minute (0.17 m^3/min) of air, may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres. See footnote 9.

9. Appropriate protection factors shall be determined, taking into account the design of the suit and its permeability to the contaminant under conditions of use. There shall be a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards and communications equipment whenever supplied-air suits are used.

10. No approval schedules are currently available for this equipment. Equipment is to be evaluated by testing or on the basis of reliable test information.

11. This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure, such as skin absorption, must be taken into account in such circumstances.

12. Quantitative fit testing shall be performed on each individual, and no more than two hundredths percent leakage is allowed with this type of apparatus. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer.

Note 1: Protection factors for respirators approved by the U.S. bureau of mines and the national institute for occupational safety and health, according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radioactive hazards. The selection and use of respirators for such circumstances should take into account applicable approvals of the U.S. bureau of mines and the national institute for occupational safety and health.

Note 2: Radioactive contaminants, for which the concentration values in table I, column 3 of appendix B of chapter 33-10-04.1.1 are based on internal dose due to inhalation,

may present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	~~1,000~~ 100	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100
Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000
Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000
Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000		
Niobium-88	1,000	Palladium-101	1,000
Niobium-89m		Palladium-103	100
(66 min)	1,000	Palladium-107	10
Niobium-89		Palladium-109	100
(122 min)	1,000	Silver-102	1,000
Niobium-90	100	Silver-103	1,000
Niobium-93m	10	Silver-104m	1,000
Niobium-94	1	Silver-104	1,000
Niobium-95m	100	Silver-105	100
Niobium-95	100	Silver-106m	100
Niobium-96	100	Silver-106	1,000
Niobium-97	1,000	Silver-108m	1
Niobium-98	1,000	Silver-110m	10
Molybdenum-90	100	Silver-111	100
Molybdenum-93m	100	Silver-112	100
Molybdenum-93	10	Silver-115	1,000
Molybdenum-99	100	Cadmium-104	1,000
Molybdenum-101	1,000	Cadmium-107	1,000
Technetium-93m	1,000	Cadmium-109	1
Technetium-93	1,000	Cadmium-113m	0.1
Technetium-94m	1,000	Cadmium-113	100
Technetium-94	1,000	Cadmium-115m	10
Technetium-96m	1,000	Cadmium-115	100
Technetium-96	100	Cadmium-117m	1,000
Technetium-97m	100	Cadmium-117	1,000
Technetium-97	1,000	Indium-109	1,000
Technetium-98	10	Indium-110	
Technetium-99m	1,000	(69.1 min)	1,000
Technetium-99	100	Indium-110	
Technetium-101	1,000	(4.9 h)	1,000
Technetium-104	1,000	Indium-111	100

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000
Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100		
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120		Iodine-131	1
(16 min)	1,000	Iodine-132m	100
Antimony-120		Iodine-132	100
(5.76 d)	100	Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128		Xenon-127	1,000
(10.4 min)	1,000	Xenon-129m	1,000
Antimony-128		Xenon-131m	1,000
(9.01 h)	100	Xenon-133m	1,000
Antimony-129	100	Xenon-133	1,000
Antimony-130	1,000	Xenon-135m	1,000
Antimony-131	1,000	Xenon-135	1,000
Tellurium-116	1,000	Xenon-138	1,000
Tellurium-121m	10	Cesium-125	1,000
Tellurium-121	100	Cesium-127	1,000
Tellurium-123m	10	Cesium-129	1,000
Tellurium-123	100	Cesium-130	1,000
Tellurium-125m	10	Cesium-131	1,000
Tellurium-127m	10	Cesium-132	100
Tellurium-127	1,000	Cesium-134m	1,000
Tellurium-129m	10	Cesium-134	10
Tellurium-129	1,000	Cesium-135m	1,000
Tellurium-131m	10	Cesium-135	100
Tellurium-131	100	Cesium-136	10
Tellurium-132	10	Cesium-137	10
Tellurium-133m	100	Cesium-138	1,000

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100
Cerium-143	100	Europium-150	
Cerium-144	1	(12.62 h)	100
Praseodymium-136	1,000	Europium-150	
Praseodymium-137	1,000	(34.2 y)	1
Praseodymium-138m	1,000	Europium-152m	100
Praseodymium-139	1,000	Europium-152	1
Praseodymium-142m	1,000	Europium-154	1
Praseodymium-142	100	Europium-155	10
Praseodymium-143	100	Europium-156	100
Praseodymium-144	1,000	Europium-157	100
Praseodymium-145	100	Europium-158	1,000
Praseodymium-147	1,000	Gadolinium-145	1,000
Neodymium-136	1,000	Gadolinium-146	10
Neodymium-138	100	Gadolinium-147	100
Neodymium-139m	1,000	Gadolinium-148	0.001
Neodymium-139	1,000	Gadolinium-149	100
Neodymium-141	1,000	Gadolinium-151	10
Neodymium-147	100	Gadolinium-152	100
Neodymium-149	1,000	Gadolinium-153	10
Neodymium-151	1,000	Gadolinium-159	100
Terbium-147	1,000	Ytterbium-162	1,000
Terbium-149	100	Ytterbium-166	100
Terbium-150	1,000	Ytterbium-167	1,000
Terbium-151	100	Ytterbium-169	100
Terbium-153	1,000	Ytterbium-175	100
Terbium-154	100	Ytterbium-177	1,000
Terbium-155	1,000	Ytterbium-178	1,000
Terbium-156m		Lutetium-169	100
(5.0 h)	1,000	Lutetium-170	100
Terbium-156m		Lutetium-171	100
(24.4 h)	1,000	Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10
Terbium-158	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100
Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000
Tantalum-182	10	Iridium-188	100
Tantalum-183	100	Iridium-189	100
Tantalum-184	100	Iridium-190m	1,000
Tantalum-185	1,000	Iridium-190	100
Tantalum-186	1,000	Iridium-192m	
Tungsten-176	1,000	(1.4 min)	10
Tungsten-177	1,000	Iridium-192	
Tungsten-178	1,000	(73.8 d)	1
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100
Rhenium-182		Platinum-193m	100
(12.7 h)	1,000	Platinum-193	1,000
Rhenium-182		Platinum-195m	100
(64.0 h)	100	Platinum-197m	1,000
Rhenium-184m	10	Platinum-197	100
Rhenium-184	100	Platinum-199	1,000
Rhenium-186m	10	Platinum-200	100
Rhenium-186	100	Gold-193	1,000
Rhenium-187	1,000	Gold-194	100
Rhenium-188m	1,000	Gold-195	10
Rhenium-188	100	Gold-198m	100
Rhenium-189	100	Gold-198	100

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Osmium-180	1,000	Gold-199	100
Osmium-181	1,000	Gold-200m	100
Osmium-182	100	Gold-200	1,000
Osmium-185	100	Gold-201	1,000
Osmium-189m	1,000	Mercury-193m	100
Osmium-191m	1,000	Mercury-193	1,000
Osmium-191	100	Mercury-194	1
Osmium-193	100	Mercury-195m	100
Osmium-194	1	Mercury-195	1,000
Iridium-182	1,000	Mercury-197m	100
Iridium-184	1,000	Mercury-197	1,000
Iridium-185	1,000	Mercury-199m	1,000
Iridium-186	100	Mercury-203	100
Iridium-187	1,000		
Thallium-194m	1,000	Francium-223	100
Thallium-194	1,000	Radium-223	0.1
Thallium-195	1,000	Radium-224	0.1
Thallium-197	1,000	Radium-225	0.1
Thallium-198m	1,000	Radium-226	0.1
Thallium-198	1,000	Radium-227	1,000
Thallium-199	1,000	Radium-228	0.1
Thallium-201	1,000	Actinium-224	1
Thallium-200	1,000	Actinium-225	0.01
Thallium-202	100	Actinium-226	0.1
Thallium-204	100	Actinium-227	0.001
Lead-195m	1,000	Actinium-228	1
Lead-198	1,000	Thorium-226	10
Lead-199	1,000	Thorium-227	0.01
Lead-200	100	Thorium-228	0.001
Lead-201	1,000	Thorium-229	0.001
Lead-202m	1,000	Thorium-230	0.001
Lead-202	10	Thorium-231	100
Lead-203	1,000	Thorium-232	100
Lead-205	100	Thorium-234	10
Lead-209	1,000	Thorium-natural	100
Lead-210	0.01	Protactinium-227	10
Lead-211	100	Protactinium-228	1
Lead-212	1	Protactinium-230	0.1
Lead-214	100	Protactinium-231	0.001
Bismuth-200	1,000	Protactinium-232	1
Bismuth-201	1,000	Protactinium-233	100
Bismuth-202	1,000	Protactinium-234	100
Bismuth-203	100	Uranium-230	0.01
Bismuth-205	100	Uranium-231	100
Bismuth-206	100	Uranium-232	0.001
Bismuth-207	10	Uranium-233	0.001
Bismuth-210m	0.1	Uranium-234	0.001
Bismuth-210	1	Uranium-235	0.001
Bismuth-212	10	Uranium-236	0.001
Bismuth-213	10	Uranium-237	100
Bismuth-214	100	Uranium-238	100
Polonium-203	1,000	Uranium-239	1,000
Polonium-205	1,000	Uranium-240	100
Polonium-207	1,000	Uranium-natural	100
Polonium-210	0.1	Neptunium-232	100
Astatine-207	100	Neptunium-233	1,000
Astatine-211	10	Neptunium-234	100
Radon-220	1	Neptunium-235	100
Radon-222	1	Neptunium-236	
Francium-222	100	(1.15E+5 y)	0.001

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX C

QUANTITIES[1] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Neptunium-236 (22.5 h)	1	Curium-242	0.01
Neptunium-237	0.001	Curium-243	0.001
Neptunium-238	10	Curium-244	0.001
Neptunium-239	100	Curium-245	0.001
Neptunium-240	1,000	Curium-246	0.001
Plutonium-234	10	Curium-247	0.001
Plutonium-235	1,000	Curium-248	0.001
Plutonium-236	0.001	Curium-249	1,000
Plutonium-237	100	Berkelium-245	100
Plutonium-238	0.001	Berkelium-246	100
Plutonium-239	0.001	Berkelium-247	0.001
Plutonium-240	0.001	Berkelium-249	0.1
Plutonium-241	0.01	Berkelium-250	10
Plutonium-242	0.001	Californium-244	100
Plutonium-243	1,000	Californium-246	1
Plutonium-244	0.001	Californium-248	0.01
Plutonium-245	100	Californium-249	0.001
Americium-237	1,000	Californium-250	0.001
Americium-238	100	Californium-251	0.001
Americium-239	1,000	Californium-252	0.001
Americium-240	100	Californium-253	0.1
Americium-241	0.001	Californium-254	0.001
Americium-242m	0.001	Einsteinium-250	100
Americium-242	10	Einsteinium-251	100
Americium-243	0.001	Einsteinium-253	0.1
Americium-244m	100	Einsteinium-254m	1
Americium-244	10	Einsteinium-254	0.01
Americium-245	1,000	Fermium-252	1
Americium-246m	1,000	Fermium-253	1
Americium-246	1,000	Fermium-254	10
Curium-238	100	Fermium-255	1
Curium-240	0.1	Fermium-257	0.01
Curium-241	1	Mendelevium-257	10
		Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

NOTE: For purposes of subdivision e of subsection 2 of section 33-10-04.1.1-13, subdivision a of subsection 5 of section 33-10-04.1.1-13, and subdivision a of subsection 1 of section 33-10-04.1.1-16 where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

[1]The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to Chapter 33-10-04.1.1, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 μCi). Values of 3.7 MBq (100 μCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000 μCi), to take into account their low specific activity.

* To convert μCi to kBq, multiply the μCi value by 37.

APPENDIX D
REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

1. Manifest

The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and United States environmental protection agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than one-tenth percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as class A, class B, or class C in subsection 1 of appendix E shall be clearly identified as such in the manifest. The total quantity of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 shall be shown. The manifest may be shipping papers used to meet United States department of transportation or United States environmental protection agency rules or requirements of the receiver, provided all the required information is included. Copies of manifests may be legible carbon copies or legible photocopies.

2. Certification

The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable rules of the United States department of transportation and the department. An authorized representative of the waste generator shall sign and date the manifest.

3. Control and tracking

a. Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs 1 through 8. Any radioactive waste generator who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of paragraphs 4 through 8. A licensee shall:

(1) Prepare all wastes so that the waste is classified according to subsection 1 of appendix E and meets the waste characteristics requirements in subsection 2 of appendix E;

(2) Label each package of waste to identify whether it is class A waste, class B waste, or class C waste, in accordance with subsection 1 of appendix E;

(3) Conduct a quality control program to ensure compliance with subsections 1 and 2 of appendix E; the program shall include management evaluation of audits;

(4) Prepare shipping manifests to meet the requirements of subsections 1 and 2;

(5) Forward a copy of the manifest to the intended recipient, at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;

(6) Include one copy of the manifest with the shipment;

(7) Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by subsection 12 of section 33-10-03-05; and

(8) For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with subdivision e.

b. Any waste collector licensee who handles only prepackaged waste shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

(2) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the

new manifest contains for each package the information specified in subsection 1. The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;

(3) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;

(4) Include the new manifest with the shipment to the disposal site;

(5) Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by subsection 12 of section 33-10-03-05, and retain information from generator manifest until ~~disposition is authorized by the department~~ the license is terminated; and

(6) For any shipments or any portion of a shipment for which acknowledgment of receipt is not received within the times set forth in this section, conduct an investigation in accordance with subdivision e.

c. Any licensed waste processor who treats or repackages wastes shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

(2) Prepare a new manifest that meets the requirements of subsections 1 and 2. Preparation of the new manifest reflects that the processor is responsible for the waste;

(3) Prepare all wastes so that the waste is classified according to subsection 1 of appendix E and meets the waste characteristics requirements in subsection 2 of appendix E;

(4) Label each package of waste to identify whether it is class A waste, class B waste, or class C waste, in accordance with subsections 1 and 3 of appendix E;

(5) Conduct a quality control program to ensure compliance with subsections 1 and 2 of appendix E.

The program shall include management evaluation of audits;

(6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;

(7) Include the new manifest with the shipment;

(8) Retain copies of original manifests and new manifests and documentation of acknowledgment of receipt as the record of transfer of licensed material required by subsection 12 of section 33-10-03-05; and

(9) For any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this section, conduct an investigation in accordance with subdivision e.

d. The land disposal facility operator shall:

(1) Acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;

(2) Maintain copies of all completed manifests or equivalent documentation until the ~~department authorizes their disposition~~ license is terminated; and

(3) Notify the shipper, that is, the generator, the collector, or processor, and the department when any shipment or portion of a shipment has not arrived within sixty days after the advance manifest was received.

e. Any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this section shall:

(1) Be investigated by the shipper if the shipper has not received notification or receipt within twenty days after transfer; and

(2) Be traced and reported to whom. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within two weeks of completion of the investigation.

APPENDIX G
REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest (Federal OMB Control Numbers 3150-0164, -0165, and -0166) reflecting information requested on applicable U.S. Nuclear Regulatory Commission (NRC) Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the department to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;
(b) LLW that is being returned to the licensee who is the ``waste generator'' or ``generator,'' as defined in this part; or
(c) Radioactively contaminated material to a ``waste processor'' that becomes the processor's ``residual waste.''

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest. NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7232.

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in

40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

As used in this appendix, the following definitions apply:

Chelating agent has the same meaning as that given in Chapter 33-10-01.

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory and process the data.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see ``high integrity container''). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under a Commission or Agreement State license who (1) is a waste generator as defined in this chapter, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of the U.S. Nuclear Regulatory Commission Requirements in 10 CFR part 61 section 56, and to meet Department of Transportation requirements for a Type A package.

Land disposal facility means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive waste. For purposes of this chapter, a "geologic

repository" as defined in 10 CFR part 60 is not considered a "land disposal facility"

NRC Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms referenced in this appendix. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package has the same meaning as that given in Chapter 33-10-01.

Physical description means the items called for on NRC Form 541 to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means NRC Form 540 and, if required, NRC Form 540A which includes the information required by DOT in 49 CFR part 172.

Source material has the same meaning as that given in Chapter 33-10-01.

Special nuclear material has the same meaning as that given in Chapter 33-10-01.

Uniform Low-Level Radioactive Waste Manifest or uniform manifest means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Waste generator means an entity, operating under a Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a ``waste generator'' if the transfer of low-level radioactive waste from its facility is defined as ``residual waste.''

Waste processor means an entity, operating under a Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically
defined media).

Information Requirements

A. General Information

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source

material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR part 61 section 55. Waste not meeting the structural stability requirements of 10 CFR par 61 section 56 subsection (b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR part 61 section 55. Waste not meeting the structural stability requirements of 10 CFR part 61 section 56 subsection (b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more ``generators'' (including ``waste generators'') as defined in this part). It also applies to mixtures of wastes shipped in an

uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained in these waste types within the disposal container. For each generator, provide the following:

   (a) The volume of waste within the disposal container;

   (b) A physical and chemical description of the waste, including the solidification agent, if any;

   (c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

   (d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR part 61 section 56 subsection (b); and

   (e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Commission. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

III. Control and Tracking

1. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this section. A licensee shall:'

(a) Prepare all wastes so that the waste is classified according to 10 CFR part 61 section 55 and meets the waste characteristics requirements in 10 CFR part 61 section 56.

(b) Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with 10 CFR part 61 section 55;

(c) Conduct a quality assurance program to assure compliance with 10 CFR part 61 section 55 and 10 CFR part 61 section 56 (the program must include management evaluation of audits);

(d) Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

(e) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (I) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (I) and (ii) is also acceptable;

(f) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

(g) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(h) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the

record of transfer of licensed material as required by 10 CFR Parts 30, 40, and 70; and

(i) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

(a) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(b) Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

(c) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either:

(1) Receipt of the manifest precedes the LLW shipment or

(2) The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

(d) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

(e) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(f) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70;

(g) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this

appendix, conduct an investigation in accordance with paragraph E of this appendix; and

(h) Notify the shipper and the Administrator of the nearest Commission Regional Office when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

(a) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(b) Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this appendix;

(c) Prepare all wastes so that the waste is classified according to 10 CFR part 61 section 55 and meets the waste characteristics requirements in 10 CFR part 61 section 56;

(d) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR part 61 section 55 and 10 CFR part 61 section 57;

(e) Conduct a quality assurance program to assure compliance with 10 CFR part 61 section 55 and 10 CFR part 61 section 56 (the program shall include management evaluation of audits);

(f) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (I) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (I) and (ii) is also acceptable;

(g) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

(h) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(i) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70;

(j) For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

(k) Notify the shipper and the Administrator of the nearest Commission Regional Office when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

(a) Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

(b) Maintain copies of all completed manifests and electronically store the information required by 10 CFR part 61 section 80 subsection (1) until the Commission terminates the license; and

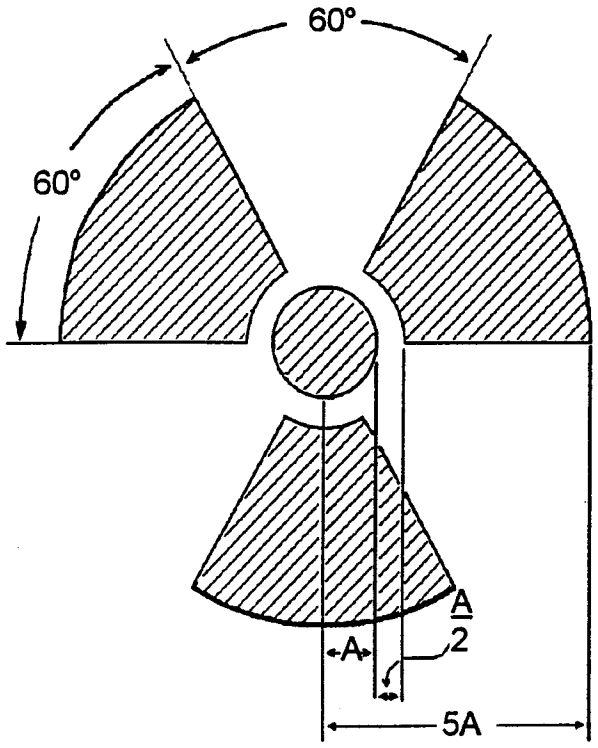
(c) Notify the shipper and the Administrator of the nearest Commission Regional Office when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

(a) Be investigated by the shipper if the shipper has not received notification or receipt within twenty days after transfer; and

(b) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest commission regional office. Each licensee who conducts a trace investigation shall file a written report with the appropriate nuclear regulatory commission regional office within two weeks of completion of the investigation.

APPENDIX H
RADIATION SYMBOL



A. Color:

1. The cross-hatched area is to be magenta, or purple, or black, and;

2. The background is to be yellow.

B. Dimensions. The dimensions of the symbol are based on the radius of the center circle (A):

1. The radius of the symbol is 5 times the radius of the center circle (5A).

2. The space between the center circle and the blades is one half of the radius of the center circle (A/2).

33-10-05-04. Equipment control.

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

   a. Each radiographic exposure device and all associated equipment must meet the requirements specified in American national ~~standard~~ standards institute (ANSI) N432-1980 "radiological safety for the design and construction of apparatus for gamma radiography", (published in NBS handbook 136, issued January 1981). Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the department may find this an acceptable alternative to actual testing of the component pursuant to the standard.

   b. In addition to the requirements specified in subdivision a, the following requirements apply to radiographic exposure devices and associated equipment.

      (1) Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:

         (a) Chemical symbol and mass number of the radionuclide in the device;

         (b) Activity and the date on which this activity was last measured;

         (c) Model number and serial number of the sealed source;

         (d) Manufacturer of the sealed source; and

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

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

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

c. In addition to the requirements specified in subdivisions a and b, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lockbox, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter.

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER RADIOACTIVE". The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must have passed the crushing tests for the control tube as specified in American national ~~standard~~ standards institute N432-1980 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

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

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

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

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

Notwithstanding subdivision a, equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the endurance test in American national standards institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

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

a. Radiographic exposure devices measuring less than ~~four inches [10 centimeters]~~ ten centimeters [4 inches] from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of ~~fifty milliroentgens [1.29 x 10^{-5} coulombs per kilogram]~~ one hundred twenty-nine ten millionths coulombs per kilogram [50 milliroentgens] per hour at ~~six inches [15 centimeters]~~ fifteen centimeters [6 inches] from any exterior surface of the device. Radiographic exposure devices measuring a minimum of ~~four inches [10 centimeters]~~ ten centimeters [4 inches] from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of ~~two hundred milliroentgens [5.16 x 10^{-5} coulombs per kilogram]~~ five hundred sixteen ten millionths coulombs per kilogram [200 milliroentgens] per hour at any exterior surface, and ~~ten milliroentgens [2.58 x 10^{-6} coulombs per kilogram]~~ two hundred fifty hundred millionths coulombs per kilogram [10 milliroentgens] per hour at ~~thirty nine and four tenths inches [1 meter]~~ one meter 39.4 inches] from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

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

3. **Locking of sources of radiation.**

a. Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer trainee, or as may be otherwise authorized pursuant to subsection 1 of section 33-10-05-06. Each storage container and source changer likewise shall be provided with a lock and must be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer trainee.

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

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

4. **Storage precautions.**

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

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

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

d. A storage or use location is permanent if radioactive material is stored at the location for more than ninety days and any one or more of the following applies to the location:

(1) Telephone service is established by the licensee.

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

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

5. **Radiation survey instruments.**

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and chapter 33-10-04.1. Instrumentation required by this subsection must have a range such that ~~two milliroentgens [5.16 x 10^{-7} coulombs per kilogram]~~ five hundred sixteen billionths coulombs per kilogram [2 milliroentgens] per hour through ~~one roentgen [2.58 x 10^{-4} coulombs per kilogram]~~ two hundred fifty millionths coulombs per kilogram [1 roentgen] per hour can be measured.

b. Each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed three months and after each instrument servicing.

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

(3) At two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logithmic scale instruments; and at appropriate points for digital instruments.

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

d. Each radiation survey instrument must be checked with a radiation source at the beginning of each day of use and at the beginning of each workshift to ensure it is operating properly.

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

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

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

c. The leak test shall be capable of detecting the presence of ~~five-thousandths--microcurie--[185---becquerels]~~ one hundred eighty-five becquerels [0.005 microcurie] of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to paragraph 5 of subdivision a of subsection 3 of section 33-10-03-05. Records of leak test results shall be kept in units of ~~microcuries-[becquerels]~~ becquerels [microcuries] and maintained for inspection by the department for two years after the required leak test is performed.

d. Any test conducted pursuant to subdivisions b and c which reveals the presence of ~~five-thousandths--microcurie--[185 becquerels]~~ one hundred eighty-five becquerels [0.005 microcurie] or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with this article. Within five days after obtaining results of the test, the licensee shall file a report with the department describing the equipment

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

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

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

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

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

b. The identity of the radiographer to whom assigned.

c. Locations where used and dates of use.

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

9. **Inspection and maintenance.**

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

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

department for two years from the date the inspection and maintenance is performed.

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

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

a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it must be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the department for two years from the date the tests were conducted.

11. **Reporting requirements.**

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

(1) Unintentional disconnection of the source assembly from the control cable.

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position.

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function.

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

(1) A description of the equipment problem.

(2) Cause of each incident, if known.

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

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

(5) Actions taken to establish normal operations.

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

(7) Qualifications of personnel involved in the incident.

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

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

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

1. **Training and testing.**

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

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

(2) The rules contained in this chapter and in the applicable sections of chapters 33-10-04.1, 33-10-10, and 33-10-13;

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

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

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

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

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

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

(3) Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments;

(4) Has demonstrated an understanding of the instructions in subdivision a of subsection 1 by successful completion of a written test and a field examination on the subjects covered; and

(5) Has successfully completed, within the last five years, an examination administered by the department or a third party designated by the department ~~after March 1, 1993~~.

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

c. Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained by the licensee or registrant for inspection by the department for three years following termination of employment.

d. Each licensee or registrant shall conduct an internal audit program to ensure that the department's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the department for two years from the date of the audit.

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

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

b. Methods and occasions for conducting radiation surveys.

c. Methods for controlling access to radiographic areas.

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

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

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

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

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

i. Maintenance of records.

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

3. **Personnel monitoring control.**

a. The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer trainee unless, at all times during radiographic operations, each such individual wears a direct-reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to at least ~~two--hundred milliroentgens--[5.6-x-10^{-5} coulombs-per-kilogram]~~ fifty-six millionths coulombs per kilogram [200 milliroentgens] and shall be recharged daily or at the start of each shift. Each badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

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

c. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus thirty percent of the true radiation exposure. Records of this check

must be maintained for inspection by the department for two years from the date of the annual check for correct response.

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

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

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

g. Each alarm ratemeter must:

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

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

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

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus twenty percent of the true radiation dose rate.

4. **Supervision of radiographer trainee.** Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools, or conducts radiation surveys required by subdivisions b and c of subsection 3 of section 33-10-05-06 to determine that the sealed source has returned to the shielded position after an exposure, the radiographer trainee shall be under the personal supervision of a radiographer instructor.

5. Identification card.

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

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

(a) The radiographer trainee training requirements in subdivision a of subsection 1.

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

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

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

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

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

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

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

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

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

1. **Security.** During each radiographic operation, the radiographer or radiographer trainee shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in chapter 33-10-01, except:

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

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

2. **Posting.** Notwithstanding any provisions in subdivision c of subsection 3 of section 33-10-04.1-13, areas in which radiography is being performed shall be conspicuously posted as required by subsection 2 of section 33-10-04.1-13.

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

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in subsection 5 of section 33-10-05-04 is available and used at each site where radiographic exposures are made.

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

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

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

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

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

4. **Documents and records required at temporary jobsites.** Each licensee or registrant conducting industrial radiography at a

temporary jobsite shall have the following records available at that site for inspection by the department:

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

b. Operating and emergency procedures.

c. Applicable rules.

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

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

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

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

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

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

(2) A current whole body personnel monitor (thermoluminescent dosimeter or film badge) for each individual;

(3) An operable, calibrated pocket dosimeter with a range of zero to ~~two hundred milliroentgens [5.16 x 10^{-5} coulombs per kilogram]~~ five hundred sixteen ten millionths coulombs per kilogram [200 milliroentgens] for each worker;

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

(5) The appropriate barrier ropes and signs.

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

c. Each licensee or registrant shall provide as a minimum two radiographic personnel when sources of radiation are used

at temporary jobsites. If one of the personnel is a radiographer trainee, the other must be a radiographer instructor.

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

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

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

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

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

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

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

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

(1) Comply with all applicable requirements of this chapter and subsection 1 of section 33-10-04.1-07. If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

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

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

(1) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and

reports of the results must be maintained for inspection by the department.

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

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

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

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

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

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

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

1. "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

2. "Added filtration" means any filtration which is in addition to the inherent filtration.

3. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is ninety-nine percent minimum aluminum, twelve-hundredths percent copper.)

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

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

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

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

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

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

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

11. "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to

allow a change in the projection of the beam through the patient without a change in the position of the patient.

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

~~12.~~ 13. "Certified components" means components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 [Pub. L. 90-602].

~~13.~~ 14. "Certified system" means any X-ray system which has one or more certified component or components.

~~14.~~ 15. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

~~15.~~ 16. "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

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

~~16.~~ 17. "Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

~~17.~~ 18. "Contact therapy system" means an X-ray system used for therapy with the X-ray tube port placed in contact with or within five centimeters of the surface being treated.

~~18.~~ 19. "Control panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

~~19.~~ 20. "Cooling curve" means the graphical relationship between heat units stored and cooling time.

~~20.~~ 21. "CT" (see "computed tomography").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~34.~~ 36. "Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the radiation exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

~~35.~~ 37. "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.

~~36.~~ 38. "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x seconds.

~~37.~~ 39. "HVL" (see "half-value layer").

~~38.~~ 40. "Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

~~39.~~ 41. "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

~~40.~~ 42. "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor ~~in a horizontal plane~~ during a mammographic examination.

~~41.~~ 43. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

~~42.~~ 44. "Irradiation" means the exposure of matter to ionizing radiation.

~~43.~~ 45. "Kilovolts peak" (see "peak tube potential").

~~44.~~ 46. "kV" means kilovolts.

~~45.~~ 47. "kVp" (see "peak tube potential").

~~46.~~ 48. "kWs" means kilowatt second. It is equivalent to 10^3 kV·mA·s, i.e.,

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

~~47.~~ 49. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

~~48.~~ 50. "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

a. The useful beam.

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

~~49.~~ 51. "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic assembly which are used in measuring leakage radiation. They are defined as follows:

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

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

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

~~50.~~ 52. "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

~~51.~~ 53. "Linear attenuation coefficient" or "u" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

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

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

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

53. 55. "mA" means (see milliampere).

54. 56. "mAs" means (see milliampere second).

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

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

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

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

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

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

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

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

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

61. 66. "PID" (see has the same meaning as "position indicating device").

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

~~63.~~ 68. "Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

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

~~64.~~ 70. "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

~~65.~~ 71. "Primary protective barrier" (see "protective barrier").

~~66.~~ 72. "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

~~67.~~ 73. "Protective barrier" means a barrier of radiation absorbing material or materials used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam~~,--for---protection purposes,-to-reduce-the-radiation-exposure.~~;

b. "Secondary protective barrier" means a~~--barrier-sufficient to-attenuate~~ the material which attenuates stray radiation ~~to-the-required-degree~~.

~~68.~~ 74. "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

~~69.~~ 75. "Qualified expert" means an individual having the knowledge ~~and~~, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American board of radiology, or the American board of health physics, or the American board of medical physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, "qualified expert" means an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in therapeutic radiological physics or X-ray and radium physics by the American board of radiology, or those having equivalent qualifications.

~~70.~~ 76. "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

~~71.~~ 77. "Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

~~72.~~ 78. "Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

~~73.~~ 79. "Radiographic imaging system" means any system whereby a permanent or ~~semipermanent~~ temporary image is recorded on an image receptor by the action of ionizing radiation.

~~74.~~ 80. "Radiological physicist" means an individual who:

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

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

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

~~75.~~ 81. "Rating" means the operating limits as specified by the component manufacturer.

~~76.~~ 82. "Recording" means producing a permanent form of an image resulting from X-ray photons.

~~77.--"Response--time"--means--the--time--required-for-an-instrument system-to-reach-ninety-percent-of-its-final-reading--when--the radiation-sensitive-volume-of-the-instrument-system-is-exposed to-a-step-change-in-radiation-flux--from--zero--sufficient--to provide-a-steady-state-midscale-reading.~~

~~78.~~ 83. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "direct scattered radiation").

~~79.~~ 84. "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

~~80.~~ 85. "Secondary protective barrier" (see "protective barrier").

~~81.~~ 86. "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

~~82.~~ 87. "SID" ~~(~~see has the same meaning as "source-image receptor distance"~~)~~.

~~83.~~ 88. "Source" means the focal spot (actual) of the X-ray tube.

~~84.~~ 89. "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

~~85.~~ 90. "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

~~86.~~ 91. "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

~~87.~~ 92. "Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

~~88.~~ 93. "SSD" means the distance between the source and the skin entrance plane of the patient.

~~89.~~ 94. "Stationary X-ray equipment" (see "X-ray equipment").

~~90.~~ 95. "Stray radiation" means the sum of leakage and scattered radiation.

~~91.~~ 96. "Technique factors" means the conditions of operation. They are specified as follows:

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

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

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

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

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

~~92.~~ 97. "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

~~93.~~ 98. "Tomogram" means the depiction of X-ray attenuation properties of a section through the body.

~~94.~~ 99. "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

~~95.~~ 100. "Tube" means an X-ray tube, unless otherwise specified.

~~96.~~ 101. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

~~97.~~ 102. "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

~~98.~~ 103. "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

~~99.~~ 104. "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given source-image receptor distance.

~~100.~~105. "Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

~~101.~~106. "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

~~102.~~107. "X-ray exposure control" means a device, switch, button, or other similar means by which ~~controls input power to the X-ray high voltage generator or the X-ray tube~~ the operator initiates or terminates, or both, the radiation exposure. It ~~includes~~ may include equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices~~, which control the technique factors of an X-ray exposure~~.

~~103.~~108. "X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

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

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

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

~~104.~~109. "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the radiation exposure rate is one-fourth of the maximum in the intersection.

~~105.~~110. "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube, high-voltage switches, electrical protective devices, and other appropriate elements.

~~106.~~111. "X-ray subsystem" means any combination of two or more components of an X-ray system.

~~107.~~112. "X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting

structures. Additional components which function with the system are considered integral parts of the system.

~~108.~~113. "X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

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

33-10-06-03. General requirements.

1. **Administrative controls.**

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

      (1) An X-ray system which does not meet the requirements of this article shall not be operated for diagnostic or therapeutic purposes~~;--if--so--directed--by--the department~~.

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

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

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

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

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

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

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

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

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

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

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

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

(c) ~~Patients~~ Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than twenty-five one-hundredths millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than ~~twenty-five one-hundredths~~ five-tenths millimeter lead equivalent

material must be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

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

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

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

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

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

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

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

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

(e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five-tenths millimeter lead equivalent material.

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

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

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

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

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

(c) Proper film handling and processing procedures~~:~~.

~~[1]--Time-temperature-film-processing-must-be-as recommended-by-the-film-manufacturer-or--as noted--in-appendix-D-for-manual-processing.~~ Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with appendix D.

~~[2]--Automatic----processors---temperature---and "replenishment-rates"-must-be-maintained-as specified--by-the-processor-manufacturer-or as-noted-in-subsection-3-of-appendix-D.~~

~~[3]--The--darkroom--integrity-must-be-maintained as-noted-in-subsection-4-of-appendix-D.~~

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

(e) X-ray systems subject to section 33-10-06-06 shall not be utilized in procedures where the

source to patient distance is less than thirty centimeters, except for veterinary systems.

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

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

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

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

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

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

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

(1) Maximum rating of technique factors.

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

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

(4) Tube rating charts and cooling curves.

(5) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system ~~after the effective date of section 33 10 06 03~~ with the names of persons who performed such services.

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

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

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

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

c. X-ray log.

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

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

2. **Plan review.**

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

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

c. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in sections 33-10-04.1-06 and 33-10-04.1-07.

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

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

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

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

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

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

5. Beam quality.

a. Half-value layer.

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

TABLE I

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts peak)	Half-value Layer (Millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

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

~~(2)--The--above--half-value--layer--(HVL)-criteria-will-be considered-to-have-been-met-if-it-can-be-demonstrated that--the-aluminum-equivalent-of-the-total-filtration in-the-primary-beam-is-not-less-than--that--shown--in table-II.~~

~~TABLE-II~~

~~Filtration-Required-vs.-Operating-Voltage~~

~~Operating-Voltage-(kVp)~~	~~Total-Filtration (inherent-plus-added) (millimeters-aluminum equivalent)~~
~~Below-50~~	~~0.5-millimeters~~

~~50---70~~	~~1.5-millimeters~~
~~Above-70~~	~~2.5-millimeters~~

~~(3)--In--addition--to-the-requirements-of-paragraph-1,-all intraoral-dental-radiographic-systems-manufactured-on and--after--December-1,--1980,--shall--have-a-minimum half-value-layer--not--less--than--one--and--one-half millimeters-----aluminum-----equivalent----filtration permanently-installed-in-the-useful-beam.~~

~~(4)~~ (2) For capacitor energy storage equipment, compliance with the requirements of this subsection shall be determined with the ~~maximum-quantity-of-charge-per exposure~~ system fully charged and a setting of ten mAs for each exposure.

~~(5)~~ (3) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always permanently present between the source and the patient.

~~(6)~~ (4) For mammography systems with molybdenum filter and molybdenum target, measured half-value layer (HVL) with compression device in the X-ray beam shall be greater than or equal to the kilovolts peak (kVp) divided by one hundred, millimeters aluminum and less than or equal to the kilovolts peak (kVp) divided by one hundred plus one-tenth millimeter aluminum.

HVL (kVP/100) mmAl and (kVp/100) + 0.1 mmAl

b. Filtration controls. For X-ray systems which have variable kilovolts peak and variable filtration for the useful beam, a device shall link the kilovolts peak selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by ~~paragraphs~~ paragraph 1 ~~or-2~~ of subdivision a is in the useful beam for the given kilovolts peak which has been selected.

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

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

8. Technique indicators.

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

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

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

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

11. Structural shielding requirements (see appendix C).

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

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

1. **Limitation of useful beam.**

   a. Primary barrier.

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

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

   b. X-ray field.

      (1) ~~The--X-ray--field--produced--by-non-image-intensified fluoroscopic-equipment-shall-not--extend--beyond--the entire--visible--area--of--the--image-receptor.--This~~

~~requirement--applies---to---field---size---for---both fluoroscopic--procedures-and-spot-filming-procedures. In-addition:~~

~~(a)--Means--shall-be-provided-for-stepless-adjustment of-the-field-size.~~

~~(b)--The---minimum---field---size---at--the--greatest source-image-receptor-distance-shall-be-equal-to or---less---than---five---centimeters---by--five centimeters.~~

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

~~(d)--Compliance---with---this---paragraph---shall--be determined-with-the-beam-axis--indicated--to--be perpendicular---to---the---plane--of--the--image receptor.~~

~~(2)~~ For ~~image-intensified~~ certified fluoroscopic ~~equipment~~ systems with or without a spot-film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the source-image receptor distance. The sum of the excess length and the excess width shall be no greater than four percent of the source-image receptor distance. ~~In-addition:~~

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

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

(4) Other requirements for fluoroscopic beam limitation:

(a) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable

source-image receptor distance and/or a visible area of greater than three hundred square centimeters shall be provided with means for stepless adjustment of the X-ray field.

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

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

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

~~(3)~~ (5) Spot-film devices ~~which are certified components~~ shall meet the following additional requirements:

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

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

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

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

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

~~(4)~~ (6) If a means exists to override any of the automatic X-ray field size adjustments required in subdivision b of subsection 1 that means:

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

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

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

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

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

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

3. **Radiation exposure rate limits.**

a. Entrance radiation exposure rate allowable limits.

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

(a) The radiation exposure measured at the point where the center of the useful beam enters the patient shall not exceed ~~ten roentgens {2.58 millicoulomb per kilogram}~~ two and fifty-eight hundredths millicoulomb per kilogram [10 roentgens] per minute, except during recording of fluoroscopic images or when provided with optional high level control.

~~(2)~~ (b) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in a radiation exposure rate in excess of ~~five roentgens {1.29 millicoulomb per kilogram}~~ one and twenty-nine hundredths millicoulomb per kilogram [5 roentgens] per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

~~(a)~~ [1] When the high level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ~~twenty roentgen {5.16 millicoulomb per kilogram}~~ five and sixteen hundredths millicoulomb per kilogram [20 roentgens] per minute at the point where the center of the useful beam enters the patient.

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

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

~~(3)~~ (2) ~~In---addition--to--the--other--requirements--of--this section,-certified~~ Fluoroscopic equipment ~~which does not--incorporate--an-automatic-exposure-control-shall not-be-operable-at-any-combination-of-tube--potential and--current--which--will--result--in--any--radiation exposure-rate--in--excess--of--five--roentgens--(1.29 millicoulomb--per--kilogram)~~ is not provided with automatic radiation exposure rate control:

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

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

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

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

~~(4)~~ (3) Compliance with the requirements of subsection 3 of this section shall be determined as follows:

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

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

(c) If the source is above the table, the radiation exposure rate shall be measured at thirty centimeters above the tabletop with the end of

the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(d) In a C-arm type of fluoroscope, both stationary and mobile units shall meet the entrance exposure rate limits specified in paragraphs 1, 2, and 3 of subdivision a of subsection 3, shall be measured thirty centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available source-image receptor distance provided that the end of the spacer assembly or beam-limiting device is not closer than thirty centimeters from the input surface of the fluoroscopic imaging assembly.

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

~~(5)~~ (4) Periodic measurement of entrance radiation exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:

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

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

(c) ~~Personnel--monitoring--devices--may--be--used-to perform----the----measurements----required----by subparagraph--a--provided--the--measurements-are made-as-described-in-subparagraph-d.~~

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

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

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

[3] The X-ray systems that incorporates automatic radiation exposure control shall have sufficient material placed in the useful beam to produce a milliamperage ~~typical of the use of the X-ray system~~ or kilovoltage, or both, to satisfy the conditions of item 2 of subparagraph c of this paragraph.

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

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

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

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

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

[4] X-ray systems that do not incorporate an automatic radiation exposure control shall utilize the maximum kVp, mA, and other

selectable parameters of clinical use of the X-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

4. **Barrier transmitted radiation rate limits.**

   a. The radiation exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, ~~if provided,~~ shall not exceed ~~two milliroentgens [0.516 microcoulomb-kilogram]~~ five hundred sixteen thousandths microcoulomb per kilogram [2 milliroentgens] per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance radiation exposure rate.

   b. Measuring compliance of barrier transmission.

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

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

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

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

      ~~(5) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.~~

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

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

   a. Thirty-eight centimeters on stationary fluoroscopes installed after ~~September 1, 1968~~ August 1, 1974.

   b. Thirty-five and one-half centimeters on stationary fluoroscopes which were in operation prior to ~~September 1, 1968~~ August 1, 1974.

   c. Thirty centimeters on all mobile fluoroscopes.

   d. Twenty centimeters for ~~image-intensified~~ all mobile fluoroscopes used for specific surgical application. ~~The written safety procedures must provide precautionary measures to be adhered to during the use of this device.~~

7. **Fluoroscopic timer.**

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

   b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

8. ~~Mobile fluoroscopes. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.~~

9. **Control of scattered radiation.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of subdivision a of this subsection, all stationary X-ray systems both certified and noncertified shall meet the following requirements:

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

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

(3) Indication of field size dimensions and source-image receptor distance's shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those

indicated by the beam-limiting device to within two percent of the source-image receptor distance when the beam axis is indicated to be perpendicular to the plane of the image receptor.

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

d. Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated source-image receptor distance except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent of the source-image receptor distance. This requirement can be met with a system which performs as prescribed in paragraph 3 of subdivision e of this subsection. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the source-image receptor distance may vary, the source-image receptor distance indication specified in subparagraphs a and b of paragraph 3 of subdivision e of this subsection shall be the maximum source-image receptor distance for which beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

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

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

distance when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

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

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

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

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and source-image receptor distance for which each aperture is designed and shall indicate which aperture is in position for use.

2. ~~Radiation-exposure-control-devices.~~

~~a.--Timers.--Means-shall-be-provided-to-terminate-the-exposure at-the-preset-time-interval,-preset-product-of-current-and time,--a--preset--number--of-pulses,-or-a-preset-radiation exposure-to-the-image-receptor.--In-addition,-it-shall-not be-possible-to-make-an-exposure-when-the-timer-is-set-to-a "zero"-or-"off"-position-if-either-position-is-provided.~~

~~b.--X-ray-control-(exposure-switch).~~

~~(1)--A-control-which-shall-be-the-equivalent-of-a-dead-man switch-shall-be-incorporated-into-each--X-ray--system~~

such that an exposure can be terminated at any time except for:

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

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

(2) Each X-ray control shall be located in such a way as to meet the following requirements:

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

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

[1] Used for greater than one week in one location (one room or suite) shall meet the requirements of subparagraph (a) of this paragraph.

[2] Used for greater than one hour and less than one week at one location, (one room or suite) shall meet the requirement of item 1 of this subparagraph or be provided with a six and one-half feet [1.98 meters] high protective barrier which is placed at least six feet [1.83 meters] from the tube housing assembly and at least six feet [1.83 meters] from the patient.

[3] Used to make an exposure of only one patient at the use location shall meet the requirement of item 1 or 2 of this subparagraph or be provided with a method of X-ray control which will permit the operator to be at least twelve feet [3.66 meters] from the tube housing assembly during an exposure.

(c) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

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

~~e.--Automatic--exposure--controls.--When-an-automatic-exposure control-is-provided:~~

~~(1)--Indication--shall--be--made-on-the-control-panel-when this-mode-of-operation-is-selected;~~

~~(2)--If--the--X-ray--tube-potential-is-equal-to-or-greater than-fifty-kilovolts-peak,-the-minimum-exposure--time for---field---emission--equipment--rated--for--pulsed operation-shall-be-equal--to--or--less--than--a--time interval-equivalent-to-two-pulses;~~

~~(3)--The--minimum--exposure--time--for-all-equipment-other than-that-specified-in-paragraph-2-shall-be-equal--to or--less--than-one-sixtieth-second-or-a-time-interval required--to--deliver---five---milliampere---seconds, whichever-is-greater;~~

~~(4)--Either--the-product-of-the-peak-X-ray-tube-potential, current,-and-exposure-time-shall-be--limited--to--not more--than-sixty-kilowatt-seconds-per-exposure-or-the product-of-X-ray-tube-current-and-exposure-time-shall be--limited--to-not-more-than-six-hundred-milliampere seconds-per--exposure--except--when--the--X-ray--tube potential--is-less-than-fifty-kilovolts-peak-in-which case-the-product-of-X-ray-tube-current--and--exposure time--shall--be-limited-to-not-more-than-two-thousand milliampere-seconds-per-exposure;-and~~

~~(5)--A--visible-signal-shall-indicate-when-an-exposure-has been-terminated-at-the-limits-required-by-paragraph-4 of--this--subdivision,--and-manual-resetting-shall-be required-before-further-automatically-timed-exposures can-be-made.~~

~~d.--Reproducibility.---With--a--timer--setting--of-five-tenths seconds-or-less,-the-average-exposure-period-(T)-shall--be greater--than--or-equal-to-five-times-the-maximum-exposure period-(Tmax)-minus-the--minimum--exposure--period--(Tmin) when-four-tests-are-performed.~~

~~T---5(Tmax --Tmin])~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FOR X-RAY FIELD LIMITATION
SYSTEM FAILURE

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

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

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

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

3. Radiation exposure control.

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

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

c. Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset

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

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

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

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

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

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

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

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

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

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

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

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

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

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

f. Operator protection, except veterinary systems.

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

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

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

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

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

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

3.- 4. **Source-to-skin distance.** All mobile or portable radiographic systems shall be provided with means to limit the

source-to-skin distance ~~to not less~~ equal to or greater than thirty centimeters, except for veterinary systems.

~~4.~~ 5. **Radiation exposure reproducibility.** ~~The~~ When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed ~~ten hundredths when all technique factors are held constant~~ five hundredths. This requirement applies to clinically used techniques. This requirement shall be deemed to have been met if, when four radiation exposures are made at identical technique factors, the value of the average radiation exposure (E) is greater than or equal to five times the maximum radiation exposure (E_{max}) minus the minimum radiation exposure (E_{min}),

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

~~5.~~ 6. **Radiation from capacitor energy storage equipment in standby status.** Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

~~6. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified components shall be required to comply with the following additional requirements which relate to those certified components.~~

~~a. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than five hundredths for any specific combination of selected technique factors.~~

~~b. Linearity. When the equipment allows a choice of X-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rating, the average ratios of radiation exposure to the indicated milliampere seconds product, (milliroentgen per milliampere second) obtained at any two consecutive tube current settings shall not differ by more than ten hundredths times their sum.~~

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

where X_1 and X_2 are the average milliroentgen per milliampere second values obtained at each of two consecutive tube current settings.

e. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

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

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

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

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

e. Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of subdivision a of subsection 1 and subdivision d of subsection 6 of section 33-10-06-06.

f. Field limitation and alignment on stationary general purpose X-ray systems. For stationary, general purpose X-ray systems which contain a tube housing assembly, an

X-ray-control,-and,--for--those--systems--so--equipped,--a table,-all-certified-in-accordance-with-21-CFR-1020.30(c).

(1)--Positive--beam-limitation-(PBL),-when-provided,-shall function-as-described-in-paragraph-2-of-subdivision-f of--subsection-6--of-section-33-10-06-06-whenever-all of-the-following-conditions-are-met:

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

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

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

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

(d)--Neither-tomographic-nor-stereoscopic-radiography is-being-performed.

(e)--Neither-tomographic-nor-stereoscopic-radiography is-being-performed.

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

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

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

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

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

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

(a)--Must--be--designed--for-use-only-in-the-event-of positive-beam-limitation-system--failure--or--if the-system-is-being-serviced.

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

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

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

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

FOR-X-RAY-FIELD-LIMITATION
SYSTEM-FAILURE

(4)--Compliance--with--paragraph-2-must-be-determined-when the--equipment--indicates--that--the--beam--axis---is perpendicular--to-the-plane-of-the-image-receptor-and the-requirements-of-paragraph-1-are-met.---Compliance must--be-determined-no-sooner-than-five-seconds-after insertion-of-the-image-receptor.

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

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

~~g.--Timers.---Except-for-dental-panoramic-systems,-termination of-exposure-shall-cause-automatic-resetting-of--the--timer to-its-initial-setting-or-to-"zero".~~

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

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

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

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

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

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

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

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

   c. Measuring compliance. Determination of compliance shall be based on four exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than forty-five hundredths millimeters

and the other is greater than forty-five hundredths millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

9. Other requirements:

~~h.~~ a. Transmission limit for image receptor supporting devices used for mammography. For X-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beams through the image receptor support provided with the system will be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed ~~one-tenth milliroentgen [25.8 microcoulomb per kilogram]~~ twenty-five and eight-tenths microcoulomb per kilogram [.01 milliroentgen] for each activation of the tube. Exposure shall be measured with the system operated at the minimum source-image receptor distance for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (milliampere second) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

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

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

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

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

a. Eighteen centimeters if operable above fifty kilovolts peak.

b. Ten centimeters if not operable above at fifty kilovolts peak only.

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

a. If the minimum source-to-skin distance (SSD) is eighteen centimeters or more, the The X-ray field beam, at the minimum source-to-skin distance, shall be containable in a circle having a diameter of no more than seven centimeters.

b. If the minimum source-to-skin distance is less than eighteen centimeters, the X-ray field, at the minimum source-to-skin distance, shall be containable in a circle having a diameter of no more than six centimeters.

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

3. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

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

b. Reproducibility. With a timer setting of five tenths seconds or less, the average exposure period (T) must be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$T \geq 5(T_{max} - T_{min})$$

4. X-ray control (exposure switch).

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

b. Each X-ray control shall be located in such a way as to meet the following criteria:

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

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

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

~~(b)--Used-for-greater-than-one-hour-and-less-than-one week-at-one-location-(one-room-or--suite)--shall meet--the-requirements-of-subparagraph-a-of-this paragraph--or--be--provided--with--a---six---and one-half-foot---[1.98-meter]----high--protective barrier-which-is-placed-at-least-six-feet--[1.83 meters]--from--the--tube-housing-assembly-and-at least-six-feet-[1.83-meters]-from-the-patient.~~

~~(c)--Used--to--make-exposures-of-a-patient-at-the-use location--shall---meet---the---requirements---of subparagraph--a--or--b--of--this-paragraph-or-be provided-with-a-method-of--X-ray--control--which will--permit--the-operator-to-be-at-least-twelve feet-[3.66-meters]-from-the-tube--head--assembly during-an-exposure.~~

~~e.--The---X-ray---control---shall--provide--visual--indication observable-at-or-from-the--operator's--protected--position whenever--X-rays--are--produced.---In--addition,--a-signal audible-to-the-operator-shall-indicate-that--the--exposure has-terminated.~~

~~5.--Exposure--reproducibility.--The-coefficient-of-variation-shall not-exceed-ten-hundredths-when-all-technique-factors-are--held constant.---This--requirement-shall-be-deemed-to-have-been-met if,-when--four--radiation--exposures--are--made--at--identical technique-factors,-the-value-of-the-average-radiation-exposure (E)-is-greater--than--or--equal--to--five--times--the--maximum radiation-exposure-(Emax) minus the minimum radiation exposure (Emin),~~

~~$$E---5(E_{max}---E_{min})$$~~

Radiation exposure control.

a. Exposure initiation.

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

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

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

c. Exposure termination.

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

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

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

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

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

where X_1 and X_2) are the average values.

e. Exposure control location and operator protection.

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

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

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

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

meters [9 feet] from the tube housing assembly while making exposures.

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

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

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

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

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

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

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

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

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

size is the nominal focal spot size specified by the X-ray tube manufacturer.

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

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

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

6. 9. **Administrative controls.**

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

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

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

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

~~7.--Additional--requirements-applicable-to-certified-systems-only.--Only--diagnostic--X-ray--systems--incorporating--one--or--more certified--components--shall--be--required--to-comply-with-the following--additional--requirements--which--relate---to---that certified-component.~~

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

~~b.--Linearity.---When--the--equipment-allows-a-choice-of-X-ray tube-current-settings-and-is-operated-on-a-power-supply-as specified--by--the--manufacturer--in--accordance--with-the requirements-of--applicable--federal--standards,--for--any fixed--X-ray--tube--potential--within--the--range-of-forty percent-to-one-hundred-percent-of-the-maximum-rating,--the average--ratios--of--radiation--exposure--to-the-indicated~~

~~milliampere-seconds-product-(milliroentgen-per-milliampere second),--obtained--at--any--two--consecutive-tube-current settings-shall-not--differ--by--more--than--ten-hundredths times-their-sum;~~

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

~~where--X_1 and-X_2 are-the-average-millirem-per-milliampere seconds-values-obtained-at-each-of--two--consecutive--tube current-settings.~~

~~e.--Accuracy.---Deviation--of-technique-factors-from-indicated values-shall-not-exceed--the--limits--specified--for--that system-by-its-manufacturer.~~

~~d.--Timers.---Termination--of--exposure--shall-cause-automatic resetting-of-the--timer--to--its--initial--setting--or--to "zero".~~

~~e.--Beam---quality.----All---certified--dental--X-ray--systems manufactured-on-and-after-December-1,-1980,-shall--have--a minimum--half-value--layer--not-less-than-one-and-one-half millimeters-aluminum-equivalent.--Systems-operating--above seventy--kilovolts--peak--are--subject--to--the-filtration requirements-of-subdivision-a-of-subsection-5--of--section 33-10-06-04.~~

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

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

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

1. **Equipment requirements.**

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

      (1) Contact therapy systems. Leakage radiation shall not exceed ~~one-hundred-milliroentgens-[25.8--microcoulomb per---kilogram---]~~ twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] per hour at five centimeters from the surface of the tube housing assembly.

(2) Zero - one hundred fifty kilovolts peak systems. Systems which are manufactured or installed prior to October 1, 1982, shall have a leakage radiation which does not exceed ~~one roentgen [0.258 millicoulomb per kilogram]~~ two hundred fifty-eight thousandths millicoulomb per kilogram [1 roentgen] in one hour at one meter from the source.

(3) Zero - one hundred fifty kilovolts peak systems. Systems which are manufactured on or after October 1, 1982, shall have a leakage radiation which does not exceed ~~one hundred milliroentgens [25.8 microcoulomb per kilogram]~~ twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] in one hour at one meter from the source.

(4) One hundred fifty-one - nine hundred ninety-nine kilovolts peak systems. The leakage radiation shall not exceed ~~one roentgen [0.258 millicoulomb per kilogram]~~ two hundred fifty-eight thousandths millicoulomb per kilogram [1 roentgen] in one hour at one meter from source except systems that operate in excess of five hundred kilovolts peak may have a leakage radiation at one meter from the source not to exceed one-tenth percent of the useful beam one meter from the source.

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

c. Removable and adjustable beam-limiting devices.

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

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

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

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

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

(2) The radiation at five centimeters from the filter insertion slot opening does not exceed ~~thirty roentgens--[7.74-millicoulomb-per-kilogram]~~ seven and seventy-four hundredths millicoulomb per kilogram [30 roentgens] per hour under any operating conditions; and

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

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

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

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

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

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

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

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

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

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

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

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

i. Timer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise

levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

b. Viewing systems.

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

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

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

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

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

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

(4) When any door referred to in paragraph 3 of this subdivision is opened while the X-ray tube is activated, the radiation exposure at a distance of one meter from the source must be reduced to less than ~~one--hundred--milliroentgens-[25.8-microcoulomb per---kilogram]~~ twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] per hour.

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

a. Surveys.

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

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

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

b. Calibration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

d. Operating procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

n. "Normal treatment distance" means:

(1) For electron irradiation, the virtual source to surface distance along the central axis of the useful

beam as specified by the manufacturer for the applicator.

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

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

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

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

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

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

2. **Requirements for equipment.**

a. Leakage radiation to the patient area.

(1) New equipment shall meet the following requirements:

(a) For all operating conditions producing maximum leakage, the absorbed dose in rads [grays] due to leakage radiation, including X-rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or the normal treatment distance and outside the maximum useful beam, shall not exceed one-tenth percent of the maximum absorbed dose in rads [grays] of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters.

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

(2) Existing equipment shall meet the following requirements:

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

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

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

(1) The absorbed dose in ~~rads-[grays]~~ grays [rads] due to leakage radiation, except in the area specified in subparagraph a of paragraph 1 of subdivision a, when measured at any point one meter from the path of charged particle, before the charged particle strikes the target or window, may not exceed one-tenth percent for X-ray leakage nor five-hundredths percent for neutron leakage of the maximum absorbed dose in ~~rads--[grays]~~ grays [rads] of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in subparagraph a of paragraph 1 of subdivision a of this subsection.

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

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

d. Filters.

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

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

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

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

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

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

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

with the filter selection operation carried out at the treatment control panel.

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

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

TABLE III

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

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

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

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

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

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

Table IV

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

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

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

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

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

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

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

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

(1) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

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

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

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

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

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

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

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

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

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

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

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

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

[4] In the event of power failure, the dose monitoring information required in this subparagraph displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty-minute period of time.

g. Beam symmetry. In new equipment inherently capable of producing useful beams with asymmetry exceeding five

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

h. Selection and display of dose monitor units.

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

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

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

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

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

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

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

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

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

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

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

l. Timer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by subsection 1 of this section.

p. Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated (the radiation detectors specified in subdivision f of

subsection 2 of section 33-10-06-09 may form part of this system). In addition:

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

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

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

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

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

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

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

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

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

c. Viewing systems.

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

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

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

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

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

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

a. Surveys.

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

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

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

b. Calibrations.

(1) The calibration of systems subject to section 33-10-06-09 shall be performed in accordance with an established calibration protocol acceptable to the department (the calibration protocol published by the American association of physicists in medicine is accepted as an established protocol. For other

protocols, the user shall submit that protocol to the department for concurrence that the protocol is acceptable) before the system is first used for irradiation of patient and thereafter at time intervals which do not exceed twelve months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

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

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

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

(b) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration.

(c) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system.

(d) Which has had constancy checks performed on the system as specified by a radiological physicist.

(4) Calibrations must be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

(5) The calibration of the therapy beam shall include but be not limited to the following determinations:

(a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the sidelight and back-pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths.

(b) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

(c) The uniformity of the radiation field and any dependency upon the direction of the useful beam.

(d) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(e) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

(6) Records of the calibration performed pursuant to paragraph 1 of this subdivision shall be maintained by the registrant for five years after completion of the full calibration.

(7) A copy of the latest calibration performed pursuant to paragraph 1 of this subdivision shall be available in the area of the control panel.

c. Spot checks. Spot checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:

(1) The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the department prior to its implementation.

(2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within fifteen days.

(3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

(4) At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.

(5) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement may not be utilized as a spot check measurement.

(6) The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

(7) Whenever a spot check indicates a significant change in operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated as required in subdivision b of subsection 4 of this section.

(8) Records of spot check measurements shall be maintained by the registrant for a period of two years after completion of the spot check measurements and any necessary corrective actions.

(9) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 4 of this section or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

(1) No individual other than the patient shall be in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system shall not be used in the administration of radiation therapy unless the requirements of subdivisions a, b, and c of this subsection have been met.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-10. Veterinary medicine radiographic installations. ~~In addition to the requirements of sections 33-10-06-03 and 33-10-06-04, the following regulations shall apply to all veterinary medicine radiographic installations:~~

~~1. Equipment.~~

~~a. The protective tube housing shall be equivalent to the requirements of subsection 3 of section 33-10-06-04.~~

b.--Diaphragms--or-cones-shall-be-provided-for-collimating-the useful-beam-to-the-area-of--clinical--interest--and--shall provide--the--same--degree-of-protection-as-is-required-of the-housing.

c.--The--total-filtration-permanently-in-the-useful-beam-shall not--be--less--than---five-tenths---millimeters---aluminum equivalent--for--machines--operating-up-to-fifty-kilovolts peak,-one-and-one-half-millimeters-aluminum-equivalent-for machines--operating--between--fifty--and-seventy-kilovolts peak,-and-two-and-one-half-millimeters-aluminum-equivalent for-machines-operating-above-seventy-kilovolts-peak.

d.--A-device-shall-be-provided-to-terminate-the-exposure-after a-preset-time-or-exposure.

e.--A--dead-man--type--of--exposure--switch-shall-be-provided, together-with-an-electrical-cord-of-sufficient-length,--so that--the-operator-can-stand-out-of-the-useful-beam-and-at least-six-feet-[1.83-meters]-from-the--animal--during--all X-ray-exposures.

2.--Structural--shielding.---All--wall,--ceiling,--and-floor-areas shall-be-equivalent-to-or-provided-with-applicable--protective barriers--as--required-in-appendix-E-of-this-chapter-to-assure compliance-with-chapter-33-10-04.1.

3.--Operating-procedures.

a.--The--operator--shall--stand-well-away-from-the-useful-beam and-the-animal-during-radiographic-exposures.

b.--No--individual--other--than--the--operator-shall-be-in-the X-ray-room-while-exposures--are--being--made--unless--such individual's-assistance-is-required.

c.--When---an---animal---must---be--held--in--position--during radiography,-mechanical-supporting-or-restraining--devices should--be--used.---If--the--animal--must--be--held--by-an individual,--that--individual--shall--be--protected---with appropriate--shielding--devices,-such-as-protective-gloves and-apron,-and-the-individual-shall-be-so-positioned--that no--part--of--the--individual's-body-will-be-struck-by-the useful-beam.---The-exposure-of-any-individual-used-for-this purpose--shall--be--monitored. Repealed effective May 1, 1998.

History: Amended-effective-June-1,-1986;-June-1,-1992;-March-1,-1994.
General Authority: NDCC-23-20.1-04
Law Implemented: NDCC-23-20.1-03,-23-20.1-04

33-10-06-11. Computed tomography X-ray systems.

1. **Definitions.** In addition to the definitions provided in sections 33-10-01-04 and 33-10-06-02, the following definitions are applicable to this section:

   a. "Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\,dz$$

   where:

   z = Position along a line perpendicular to the tomographic plane.
   D(z) = Dose at position z.
   T = Nominal tomographic section thickness.
   n = Number of tomograms produced in a single scan.

   This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

   b. "Contrast scale" means the change in the linear attenuation coefficient per computed tomography number relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

   where:

   u_x = Linear attenuation coefficient of the material of interest.
   u_w = Linear attenuation coefficient of water.
   $(CTN)_x$ = CTN of the material of interest.
   $(CTN)_w$ = CTN of water.

   c. "CS" (See "Contrast scale").

   d. "CT" means a radiologic imaging technique that produces images of "slices" through a patient's body.

   e. "CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in section 33-10-06-02.

   f. "CTDI" (See "Computed tomography dose index").

g. "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

h. "CTN" (See "CT number").

i. "CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant (The constant has a normal value of one thousand when the Houndsfield scale of CTN is used.)
u_x = Linear attenuation coefficient of the material of interest.
u_w = Linear attenuation coefficient of water.

j. "Dose profile" means the dose as a function of position along a line.

k. "Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted. (See also "Picture element").

l. "Multiple tomogram system" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

m. "Noise" means the standard deviation of the fluctuations in computed tomography number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS = Contrast scale.
u_w = Linear attenuation coefficient of water.
s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

n. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at

the center of the cross-sectional volume over which X-ray transmission data are collected.

o. "Picture element" means an elemental area of a tomogram.

p. "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

q. "Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

r. "Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

s. "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

t. "Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

u. "Single tomogram system" means CT a X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

v. "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

w. "Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

2. **Requirements for equipment.**

a. Termination of exposure.

(1) Means must be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination must occur within an interval that limits the total scan time to no more than one hundred ten percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(2) A visible signal must indicate when the X-ray exposure has been terminated through the means required by paragraph 1.

(3) The operator must be able to terminate the X-ray exposure at any time during a scan, or series of scans under computed tomography X-ray system control, of greater than one-half second duration.

b. Tomographic plane indication and alignment.

(1) For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means ~~must~~ shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(3) If a device using a light source is used to satisfy paragraph 1 or 2, the light source must provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to five hundred lux.

c. Beam-on and shutter status indicators and control switches.

(1) The computed tomography X-ray control and gantry must provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) Each emergency button or switch must be clearly labeled as to its function.

d. Indication of computed tomography conditions of operation. The computed tomography X-ray system must be designed such that the computed tomography conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of computed tomography conditions of operation must be visible from any position from which scan initiation is possible.

e. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port may not exceed that permitted by subsection 3 of section 33-10-06-04.

f. Maximum surface computed tomography dose index identification. The angular position where the maximum surface computed tomography dose index occurs must be identified to allow for reproducible positioning of a computed tomography dosimetry phantom.

g. Additional requirements applicable to computed tomography X-ray systems containing a gantry manufactured after September 3, 1985.

(1) The total error in the indicated location of the tomographic plane or reference plane may not exceed five millimeters.

(2) If the X-ray production period is less than one-half second, the indication of X-ray production must be actuated for at least one-half second. Indicators at or near the gantry must be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The deviation of indicated scan increment versus actual increment may not exceed plus or minus one millimeter with any mass from zero to one hundred kilograms resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or thirty centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(4) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the computed tomography conditions of operation prior to the initiation of another scan.

h. Facility design requirements.

(1) Aural communication. Provision must be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

(a) Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous observation of the patient during irradiation and must be so located that the operator can observe the patient from the control panel.

(b) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) must be available for use in the event of failure of the primary viewing system.

i. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

(a) All computed tomography X-ray systems installed after March 1, 1992, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys must be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(b) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report must be made available to the department upon request.

(2) Radiation calibrations.

(a) The calibration of the radiation output of the computed tomography X-ray system must be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

(b) The calibration of a computed tomography X-ray system must be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

(c) The calibration of the radiation output of a computed tomography X-ray system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years.

(d) Computed tomography dosimetry phantoms must be used in determining the radiation output of a computed tomography X-ray system. Such phantoms must meet the following specifications and conditions of use:

[1] Computed tomography dosimetry phantoms must be right circular cylinders of polymethyl methacrylate of density one point nineteen plus or minus point zero one grams per cubic centimeter. The phantoms must be at least fourteen centimeters in length and must have diameters of thirty-two centimeters for testing computed tomography X-ray systems designed to image any section of the body and sixteen centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

[2] Computed tomography dosimetry phantoms must provide means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation one centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

[3] Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

[4] All dose measurements must be performed with the computed tomography dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(e) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(f) Calibration must meet the following requirements:

[1] The dose profile along the center axis of the computed tomography dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination must be

performed for each available nominal tomographic section thickness.

[2] The computed tomography dose index (For the purpose of determining the computed tomography dose index, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) along the two axes specified in item 2 of subparagraph d must be measured. The computed tomography dosimetry phantom must be oriented so that the measurement point one centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface computed tomography dose index identified. The computed tomography conditions of operation must correspond to typical values used by the registrant.

[3] The spot checks specified in paragraph 3 of subdivision i must be made.

(g) Calibration procedures must be in writing. Records of calibrations performed must be maintained for inspection by the department.

(3) Spot checks.

(a) The spot check procedures must be in writing and must have been developed by a qualified expert.

(b) The spot check procedures must incorporate the use of a computed tomography dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean computed tomography number for water or other reference material.

(c) All spot checks must be included in the calibration required by paragraph 2 and at time intervals and under system conditions specified by a qualified expert.

(d) Spot checks must include acquisition of images obtained with the computed tomography dosimetry phantoms using the same processing mode and computed tomography conditions of operation as are used to perform calibrations required by

paragraph 2 of subdivision i. The images must be retained, until a new calibration is performed, in two forms as follows:

[1] Photographic copies of the images obtained from the image display device; and

[2] Images stored in digital form on a storage medium compatible with the computed tomography X-ray system.

(e) Written records of the spot checks performed shall be maintained for inspection by the department.

(4) Operating procedures.

(a) The computed tomography X-ray system may not be operated except by an individual who has been specifically trained in its operation.

(b) Information must be available at the control panel regarding the operation and calibration of the system. Such information must include the following:

[1] Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

[2] Instructions on the use of the computed tomography dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

[3] The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

[4] A current technique chart available at the control panel which specifies for each routine examination the computed tomography conditions of operation and the number of scans per examination.

(c) If the calibration or spot check of the computed tomography X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the

computed tomography X-ray system on patients must be limited to those uses permitted by established written instructions of the qualified expert.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

APPENDIX 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. All films shall be processed in such a fashion as to achieve adequate sensitometric performance. This criterion shall be adjudged to have been met if either of the following items can be met:~~

~~a. Film manufacturers published recommendations as regards time and temperature are followed, or~~

~~b. Each film shall be developed in accord with the above time-temperature chart.~~

~~2~~1. Manual processing of film.

a. Where film is developed manually, ~~a system shall be available which consists of at least one three-sectional tank~~ processing tanks should be made of mechanically rigid, corrosion resistant material ~~(each section of which shall be constructed so as to retain its solution separation from the other two)~~ and the temperature of solutions in the tanks shall be maintained ~~has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall~~ 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).

~~c. Chemical-film processing control.~~

~~(1) Chemicals shall be mixed in accord with the chemical manufacturer's recommendations.~~

~~(2) Developer replenisher shall be periodically added to the developer tank based on the area of the films which have been developed, e.g., one liter per three thousand one hundred square inches [2 square meters] of film or in accord with the recommendations of the chemical manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.~~

~~(3) All processing chemicals shall be completely replaced at least every three months.~~

~~(4) At the time of the complete processing chemical change, a film shall be exposed to a density of approximately one, with one-half of the film being protected from the exposure. After full development, it will be maintained in the darkroom or vicinity and at the beginning of each work day at least one test film or film strip (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 developing results and base fog level.~~

~~3~~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.

~~a~~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.

~~b~~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. Darkrooms.~~

~~a. Darkrooms shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through a safelight filter.~~

~~b. The radiance and spectral emission of the safelight (bulb and filter combination) shall be such that film shall not be "fogged" above the base level when exposed for one minute at a distance of about one hundred twenty centimeters from the lamp or lamps. Film manufacturer's recommendations for a safelight and its placement shall be adjusted to meet this criterion.~~

4. Other Requirements:

a. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in

density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

c. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

d. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

e. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

f. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

g. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

APPENDIX E
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the department approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A detailed description of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. Any evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert on the X-ray systems to be used in the screening program. The evaluation by the qualified expert shall show that such systems do satisfy all requirements of this article. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the diagnostic X-ray ~~film~~ 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; amended effective May 1, 1998.

APPENDIX F

~~INSTRUCTION OF USERS OF X-RAY EQUIPMENT IN THE HEALING ARTS~~

DETERMINATION OF COMPETENCE

The Department may use interview, observation and/or testing to determine compliance. The following are areas in which an individual shall have expertise for the competent operation of X-ray equipment:

1. Fundamentals of radiation safety.

   a. Characteristics of X-radiation.
   b. Units of radiation dose (mrem).
   c. Hazards of ~~excessive~~ 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. Radiation detection instrumentation to be used.~~

~~a. Radiation survey instruments.~~

~~(1) Operation.~~
~~(2) Calibration.~~
~~(3) Limitation.~~

~~b. Survey, monitoring, and spot check techniques.~~
~~c. Personnel monitoring devices.~~

~~(1) Film badges.~~
~~(2) Pocket dosimeters.~~
~~(3) Thermoluminescent dosimeters.~~

~~d. Interpretation of personnel monitoring reports.~~

~~3. Operation and control of X-ray equipment.~~

~~a. Collimation and Filtration.~~
~~b. Exposure techniques for the equipment used.~~
~~c. Film processing techniques.~~
~~d. Anatomy and positioning.~~

~~(1) Relevant human anatomy.~~
~~(2) Relevant human physiology.~~
~~(3) Radiographic positioning.~~

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.

~~4~~7. The requirements of pertinent federal and state rules.

~~5~~8. The licensee's or registrant's written operating and emergency procedures.

History: Effective June 1, 1986; amended effective June 1, 1992; May 1, 1998.

CHAPTER 33-10-07

33-10-07-01.1. Definitions. As used in this chapter, the following definitions apply:

1. "Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

2. ~~"As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical.~~ "Authorized nuclear pharmacist" means a pharmacist who is:

   a. ~~Consistent with the purpose for which the licensed activity is undertaken~~ Board certified as a nuclear pharmacist by the board of pharmaceutical specialties;

   b. ~~Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations; and~~ Identified as an authorized nuclear pharmacist on a United States nuclear regulatory commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or

   c. ~~In relation to utilization of nuclear energy in the public interest.~~ Identified as an authorized nuclear pharmacist on a permit issued by a United States nuclear regulatory commission or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

3. "Authorized user" means a ~~practitioner of the healing arts who is identified as an authorized user on a department [agreement state, licensing state or United States nuclear regulatory commission] license that authorizes the medical use of radioactive material.~~ physician, dentist, or podiatrist who is:

   a. Board certified by at least one of the following boards:

      (1) American board of nuclear medicine.

      (2) American board of radiology.

      (3) American osteopathic board of nuclear medicine.

      (4) American osteopathic board of radiology.

(5) British facility of radiology or British royal college of radiology.

(6) Canadian royal college of physicians and surgeons;

b. Identified as an authorized user on a United States nuclear regulatory commission or agreement state license that authorizes the medical use of radioactive material; or

c. Identified as an authorized user on a permit issued by a United States nuclear regulatory commission or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

4. "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

5. "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

6. "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

7. "Management" means the chief executive officer or that individual's designee.

8. "Medical institution" means an organization in which several medical disciplines are practiced.

9. "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to ~~humans--in--the--practice--of-the-healing-arts~~ patients or human research subjects under the supervision of an authorized user.

10. "Misadministration" means the administration of:

a. A radiopharmaceutical dosage greater than ~~thirty microcuries-[1110-kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131:

(1) Involving the wrong ~~patient~~ individual or wrong radiopharmaceutical; or

(2) When both the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds ~~thirty-microcuries-[1110-kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries].

b. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(1) Involving the wrong ~~patient~~ individual, wrong radiopharmaceutical, or wrong route of administration; or

(2) When the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage.

c. A gama stereotactic radiosurgery radiation dose:

(1) Involving the wrong ~~patient~~ individual or wrong treatment site; or

(2) When the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.

d. A teletherapy radiation dose:

(1) Involving the wrong ~~patient~~ individual, wrong mode of treatment, or wrong treatment site;

(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;

(3) When the calculated weekly administered dose ~~is~~ exceeds the weekly prescribed dose by thirty percent ~~greater--than~~ or more of the weekly prescribed dose; or

(4) When the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose.

e. A brachytherapy radiation dose:

(1) Involving the wrong ~~patient~~ individual, wrong radioisotope, or wrong treatment site (excluding, for

permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(2) Involving a sealed source that is leaking;

(3) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(4) When the calculated administered dose differs from the prescribed dose by more than twenty percent of the prescribed dose.

f. A diagnostic radiopharmaceutical dosage, other than quantities greater than ~~thirty---microcuries---[1110 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131, both:

(1) Involving the wrong ~~patient~~ individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(2) When the dose to the ~~patient~~ individual exceeds ~~five rems-[50-millisieverts]~~ fifty millisieverts [5 rems] effective dose equivalent or ~~fifty--rems--[500 millisieverts]~~ five hundred millisieverts [50 rems] dose equivalent to any individual organ.

11. "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

12. "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

13. "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

14. "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

a. In a written directive; or

b. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

~~14.~~ 15. "Prescribed dose" means:

a. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

b. For teletherapy, the total dose and dose per fraction as documented in the written directive; or

c. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

~~15.~~ 16. "Recordable event" means the administration of:

a. A radiopharmaceutical or radiation without a written directive where a written directive is required;

b. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

c. A radiopharmaceutical dosage greater than ~~thirty microcuries [1110 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131 when both:

(1) The administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage; and

(2) The difference between the administered dosage and prescribed dosage exceeds ~~fifteen microcuries [555 kilobecquerels]~~ five hundred fifty-five kilobecquerels [15 microcuries];

d. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administrated dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;

e. A teletherapy radiation dose when the calculated weekly administered dose ~~is~~ exceeds the weekly prescribed dose by fifteen percent ~~greater than~~ or more of the weekly prescribed dose; or

f. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

~~16.~~ 17. "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

~~17.~~ 18. "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.

~~18.~~ 19. "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

~~19.~~ 20. "Written directive" means an order in writing for a specific patient, or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in subdivision f, containing the following information:

a. For any administration of quantities greater than ~~thirty microcuries [1110 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131: the dosage;

b. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

c. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

d. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

e. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

f. For all other brachytherapy:

(1) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(2) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-03.1. General regulatory requirements.

1. **License required.**

a. No person may manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to this article.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with this chapter under the supervision of an authorized user as provided in subsection 5 of section 33-10-07-04.

c. Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with this chapter under the supervision of an authorized nuclear pharmacist or authorized users as provided in subsection 5 of section 33-10-07-04.

2. **License amendments.** A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this chapter;

b. ~~Before permitting anyone, except a visiting authorized user described in subsection 6 of section 33-10-07-04, to work as an authorized user under the license;~~ Before the licensee permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

(1) An authorized user certified by one of the following organizations:

(a) American board of nuclear medicine.

(b) American board of radiology.

(c) American osteopathic board of nuclear medicine.

(d) American osteopathic board of radiology.

(e) British faculty of radiology or British royal college of radiology.

(f) Canadian royal college of physicians and surgeons;

(2) An authorized nuclear pharmacist certified by the board of pharmaceutical specialties;

(3) Identified as an authorized user or an authorized nuclear pharmacist on a United States nuclear regulatory commission or an agreement state license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

(4) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a United States nuclear regulatory commission or an agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

c. Before changing a radiation safety officer or teletherapy physicist;

d. ~~Before--receiving--radioactive--material--in-excess-of-the amount-authorized--on--the--license~~ Before the licensee orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license;

e. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

3. **Notifications.** ~~A--licensee--shall--notify--the-department-in writing-within-thirty-days-when-an-authorized-user,--radiation safety---officer,---or---teletherapy---physicist,--permanently discontinues-performance-of-duties-under-the-license.~~

a. A licensee shall provide to the department a copy of the board certification, the United States nuclear regulatory commission or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than thirty days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to subdivision b of subsection 2.

b. A licensee shall notify the department by letter no later than thirty days after:

(1) An authorized user, an authorized nuclear pharmacist, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

4. Exemptions regarding type A specific licenses of broad scope. A licensee possessing a type A specific license of broad scope for medical use is exempt from the following:

a. The provisions of subdivision b of subsection 2;

b. The provisions of subdivision e of subsection 2 regarding additions to or changes in the areas of use only at the addresses specified in the license;

c. The provisions of subdivision a of subsection 3; and

d. The provisions of paragraph 1 of subdivision b of subsection 3 for an authorized user or an authorized nuclear pharmacist.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-04. Additional requirements.

1. **As low as** is reasonably achievable program.

   a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable in accordance with subsection 2 of section 33-10-04.1-05.

   b. To satisfy the requirement of subdivision a:

      (1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this article or the radiation safety committee; or

      (2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

   c. The as low as is reasonably achievable program must include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as is reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the as low as is reasonably achievable program for the duration of the license. The written description must include:

(1) A commitment by management to keep occupational doses as low as is reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels as established in accordance with the requirements of paragraph 8 of subdivision b of subsection 3 that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and consideration of actions that might be taken to reduce the probability of recurrence.

2. **Radiation safety officer.**

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

(a) Authorizing the purchase of radioactive material;

(b) Receiving and opening packages of radioactive material;

(c) Storing radioactive material;

(d) Keeping an inventory record of radioactive material;

(e) Using radioactive material safely;

(f) Taking emergency action if control of radioactive material is lost;

(g) Performing periodic radiation surveys;

(h) Performing checks and calibrations of survey instruments and other safety equipment;

(i) Disposing of radioactive material;

(j) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(k) Keeping a copy of all records and reports required by this article, a copy of this article, a copy of each licensing request and license and amendments, and the written policy and procedures required by this article; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the department for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

3. **Radiation safety committee.** Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) To establish a quorum and to conduct business, one-half of the committee's membership must be present, including the radiation safety officer and the management's representative.

(4) The minutes of each radiation safety committee meeting must include:

(a) The date of the meeting;

(b) Members present;

(c) Members absent;

(d) Summary of deliberations and discussions;

(e) Recommended actions and the numerical results of all ballots; and

(f) Document any reviews required in subdivision c of subsection 1 and subdivision b of this subsection.

(5) The committee shall provide each member with a copy of the meeting minutes, and retain one copy until the department authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as is reasonably achievable;

(2) (a) Review, on the basis of safety and with regard to the training and experience standards of this ~~part~~ chapter, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

(b) Review, pursuant to subdivision b of subsection 2 of section 33-10-07-03.1, on the basis of the board certification, the license, or the permit identifying an individual and approve or disapprove any individual prior to allowing that individual to work as an

authorized user or authorized nuclear pharmacist;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the department for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

4. **Statement of authorities and responsibilities.**

a. A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of corrective actions.

b. A licensee shall establish, in writing, the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.

5. **Supervision.**

a. A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under

the supervision of an authorized user as allowed by section 33-10-07-03.1 shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients or human research subjects.

b. A licensee shall require the supervised individual receiving, possessing, using, or transferring radioactive material under section 33-10-07-03.1 to:

(1) Follow the instructions of the supervising authorized user;

(2) Follow the written radiation safety and quality management procedures established by the licensee; and

(3) Comply with this article and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by subdivision c of subsection 1 of section 33-10-07-03.1, shall:

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program,

as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions given pursuant to paragraph 1 and to comply with this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that permits supervision of an individual is responsible for the acts and omissions of the supervised individual.

6. ~~Visiting authorized user.~~

~~a. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:~~

~~(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;~~

~~(2) The licensee has a copy of an agreement state, licensing state, or United States nuclear regulatory commission license that identifies the visiting authorized user by name as an authorized user for medical use; and~~

~~(3) Only those procedures for which the visiting authorized user is specifically authorized by an agreement state, licensing state, or United States nuclear regulatory commission license are performed by that individual.~~

~~b. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in subdivision a.~~

~~c. A licensee shall retain copies of the records specified in subdivision a for five years from the date of the last visit.~~

7. **Mobile nuclear medicine service administrative requirements.**

a. The department will only license mobile nuclear medicine services in accordance with this chapter and other

applicable requirements of this article to serve clients who do not have a department license.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.

c. A mobile nuclear medicine service may not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

~~8.~~ 7. **Quality management program.**

a. Each applicant or licensee under this chapter, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive is prepared for:

(a) Any teletherapy radiation dose;

(b) Any gamma stereotactic radiosurgery radiation dose;

(c) Any brachytherapy radiation dose;

(d) Any administration of quantities greater than ~~thirty--microcuries--[1110--kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] of either sodium iodide I-125 or I-131; or

(e) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.

(If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within forty-eight hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within twenty-four hours of the oral directive.)

(2) That, prior to each administration, the patient's <u>or human research subject's</u> identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

b. The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, and evaluation of:

(a) A representative sample of patient <u>and human research subject</u> administrations;

(b) All recordable events; and

(c) All misadministrations;

to verify compliance with all aspects of the quality management program (these reviews must be conducted at intervals no greater than twelve months);

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subdivision a of this section; and

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

c. The licensee shall evaluate and respond, within thirty days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

d. The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph 1 of subdivision a, in an auditable form, for three years after the date of administration.

e. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the department within thirty days after the modification has been made.

f. (1) Each applicant for a new license, as applicable, shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.

(2) Each existing licensee, as applicable, shall submit to the department by January 1, 1995, a written certification that the quality management program has been implemented along with a copy of the program.

9. 8. **Notifications, reports, and records of misadministrations.**

a. For a misadministration:

(1) The licensee shall notify the department by telephone no later than the next working day after discovery of the misadministration.

(2) The licensee shall submit a written report to the department within fifteen days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the ~~patient~~ individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the ~~patient~~ individual, or the ~~patient's~~ individual's responsible relative or guardian ~~(this person will be subsequently referred to as "the patient" in this subsection)~~, and if not, why not;; and if the ~~patient~~ there was ~~notified~~ notification, what information was provided ~~to the patient~~. The report must not include the ~~patient's~~ individual's name or other information that could lead to identification of the ~~patient~~ individual. To meet the requirements of this subsection, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the ~~patient~~ individual receiving the misadministration of the misadministration no later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that the referring physician will inform the ~~patient~~ individual or that, based on medical judgment, telling the ~~patient~~ individual would be harmful. The licensee is not required to notify the ~~patient~~ individual without first consulting the referring physician. If the referring physician or ~~patient~~ individual receiving the misadministration cannot be reached within twenty-four hours, the licensee shall notify the ~~patient~~ individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the ~~patient~~ individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the ~~patient~~ individual who received the misadministration was notified, the licensee shall also furnish, within fifteen days after discovery of the misadministration, a written report to the ~~patient~~ individual by sending either:

(a) A copy of the report that was submitted to the department; or

(b) A brief description of both the event and the consequences as they may affect the ~~patient~~ individual, provided a statement is included that the report submitted to the department can be obtained from the licensee.

b. Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the ~~patient~~ individual who received the misadministration, and ~~the patient's~~ that individual's referring physician if applicable), the ~~patient's~~ individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the ~~patient~~ individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

c. Aside from the notification requirement, nothing in this ~~section~~ subsection affects any rights or duties of licensees and physicians in relation to each other, ~~patients~~ to individuals receiving misadministrations, or ~~the patient's~~ to that individual's responsible relatives or guardians.

~~10.~~ 9. Suppliers for sealed sources or devices for medical use. A licensee shall use for medical use only:

a. ~~Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent rules of another agreement state, a licensing state, or the United States nuclear regulatory commission; and~~ Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to chapter 33-10-03 and subdivision j of subsection 5 of section 33-10-03-05, 10 CFR part 30 and 10 CFR 32.74, or the equivalent requirements of another agreement state or a licensing state; or

b. ~~Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the United States food and drug administration.~~

c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to this article, or the equivalent rules of another agreement state, a licensing state, or the United States nuclear regulatory commission.

10. Provisions for research involving human subjects. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a federal agency which has implemented the federal policy for the protection of human subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its department license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "institutional review board" in accordance with the meaning of these terms as defined and described in the federal policy for the protection of human subjects.

11. Food and drug administration and other federal and state requirements. Nothing in this chapter relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs or devices.

History: Effective June 1, 1992; amended effective March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-05. Specific requirements.

1. **Quality control of imaging equipment.** Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures must include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the department. The licensee shall conduct quality control procedures in accordance with written procedures.

2. **Possession, use, calibration, and check of dose calibrators.**

   a. ~~A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient.~~ A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.

   b. A licensee shall:

      (1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting

with a sealed source of not less than ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] of radium-226 or ~~fifty microcuries [1.85 megabecquerels]~~ one thousand eight hundred fifty kilobecquerels [50 microcuries] of any other photon-emitting radionuclide with a half-life greater than ninety days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed twelve months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within five percent of the stated activity, with minimum activity of ~~ten microcuries [370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] for radium-226 and ~~fifty microcuries [1.85 megabecquerels]~~ one thousand eight hundred fifty kilobecquerels [50 microcuries] for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between one hundred thousand electron volts and five hundred thousand electron volts;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between ~~ten microcuries [370 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] and the highest dosage that will be administered to a patient or human research subject; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ten percent if the dosage is greater than ~~ten microcuries [370 kilobecquerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries] and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent.

d. A licensee shall also perform checks and tests required by subdivision b following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by this section for ~~two~~ three years. The records required by subdivision b must include:

(1) For paragraph 1 of subdivision b, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For paragraph 2 of subdivision b, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, ~~the instrument settings,~~ and the ~~signature of the radiation safety officer~~ identity of the individual performing the test;

(3) For paragraph 3 of subdivision b, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the ~~signature of the radiation safety officer~~ identity of the individual performing the test; and

(4) For paragraph 4 of subdivision b, the model and serial number of the dose calibrator, the configuration ~~and calibrated activity~~ of the source measured, ~~the activity of the source,~~ the activity measured ~~and the instrument setting~~ for each volume measured, the date of the test, and the ~~signature of the radiation safety officer~~ identity of the individual performing the test.

3. Possession, use, calibration, and check of instruments to measure dosages of alpha-emitting or beta-emitting radionuclides.

a. This subsection does not apply to unit dosages of alpha-emitting or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent regulations of an agreement state or a licensing state.

b. For other than unit dosages obtained pursuant to subdivision a, a licensee shall possess and use instrumentation to measure the radioactivity of alpha-emitting or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations the amount of radioactivity in dosages of alpha-emitting or beta-emitting radionuclides prior to

administration to each patient or human research subject. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for consistency and proper operation at the beginning of each day of use.

4. **Calibration and check of survey instruments.**

a. A licensee shall ensure that the survey instruments used to show compliance with this section have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of subdivision a the licensee shall:

(1) Calibrate all required scale readings up to ~~one thousand millirems [10 millisieverts]~~ ten millisieverts [1000 millirems] per hour with a radiation source;

(2) For each scale that must be calibrated, calibrate two readings separated by at least fifty percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of subdivision b, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than twenty percent, and shall conspicuously attach a correction chart or graph to the instrument.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in subdivision a for ~~two~~ three years. The record must include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of subdivisions a, b, and c the licensee may obtain the services of individuals licensed by the department, the United States nuclear regulatory commission, and agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by subdivision e must be maintained by the licensee.

4. 5. **Assay of radiopharmaceutical dosages.** A licensee shall:

a. ~~Assay, within thirty minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than ten microcuries [370 kilobecquerels] of a photon-emitting radionuclides;~~ Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use.

b. ~~Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of ten microcuries [370 kilobecquerels] or less of a photon-emitting radionuclide to verify that the dosage does not exceed ten microcuries [370 kilobecquerels[;~~ and Measure by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha-emitting or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 37.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements;

c. Retain a record of the assays measurements required by subdivisions a and b for ~~two~~ three years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of assay measurement, or a notation that the total activity is less than ~~ten microcuries [370~~

~~kilobeequerels]~~ one thousand one hundred ten kilobecquerels [30 microcuries];

(4) Date and time of the ~~assay--and--administration~~ measurement; and

(5) Initials of the individual who ~~performed-the-assay~~ made the record.

~~5.~~ 6. **Authorization for calibration and reference sources.** Any person authorized by subsection 1 of section 33-10-07-03.1 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to chapter 33-10-03 or equivalent provisions of the United States nuclear regulatory commission, agreement state, or licensing state and that do not exceed ~~fifteen--millicuries--[555 megabeequerels]~~ five hundred fifty-five megabecquerels [15 millicuries] each;

b. Any radioactive material listed in sections 33-10-07-06 and 33-10-07-07 with a half-life of one hundred days or less in individual amounts not to exceed ~~fifteen millicuries--[555-megabeequerels]~~ five hundred fifty-five megabecquerels [15 millicuries];

c. Any radioactive material listed in sections 33-10-07-06 and 33-10-07-07 with a half-life greater than one hundred days in individual amounts not to exceed ~~two-hundred microcuries--[7.4--megabeequerels]~~ seven thousand four hundred kilobecquerels [200 microcuries] each; and

d. Technetium-99m in individual amounts not to exceed ~~fifty millicuries--[1.85--gigabeequerels]~~ one thousand eight hundred fifty megabecquerels [50 millicuries].

~~6.~~ 7. **Requirements for possession of sealed sources and brachytherapy sources.**

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the department and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall assure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the department, another agreement state, a licensing state, or the United States nuclear regulatory commission.

c. To satisfy the leak test requirements of subdivision b, the licensee shall assure that:

(1) Leak tests are capable of detecting the presence of ~~five--thousandths--microcurie--{185--becquerels}~~ one hundred eighty-five becquerels [0.005 microcuries] of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of ~~one----thousandth----microcurie----{37----becquerels}~~ thirty-seven becquerels [0.001 microcurie] per twenty-four hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the "off" position.

d. A licensee shall retain leak test records for five years. The records must contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in ~~microcuries--{becquerels}~~ becquerels [microcuries], a description of the method used to measure each test sample, the date of the test, and the signature of the radiation safety officer.

e. If the leak test reveals the presence of ~~five-thousandths microcurie--{185--becquerels}~~ one hundred eighty-five becquerels [0.005 microcurie] or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these regulations; and

(2) File a report with the department within five days of receiving the leak test results describing the

equipment involved, the test results, and the action taken.

f. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than thirty days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing ~~one--hundred--microcuries--[3.7 megabecquerels]~~ three thousand seven hundred kilobecquerels [100 microcuries] or less of beta or photon-emitting material or ~~ten--microcuries--[370 kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the radiation safety officer.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in subdivision h for ~~two~~ three years. The record must include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in ~~millirems---[microsieverts]~~ microsieverts [millirems] per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

~~7.~~ 8. **Syringe shields.**

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

~~8.~~ 9. **Syringe labels.** Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

~~9.~~ 10. **Vial shields.** A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

~~10.~~ 11. **Vial shield labels.** A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

~~11.~~ 12. **Surveys for contamination and ambient radiation dose rate.**

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by subdivisions a and b so as to be able to measure dose rates as low as ~~one-tenth millirem [1 microsievert]~~ one microsievert [0.1 millirem] per hour.

d. A licensee shall establish dose rate action levels for the surveys required by subdivisions a and b and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are

routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by subdivision e so as to be able to detect contamination on each wipe sample of two thousand disintegrations per minute [33.3 becquerels].

g. A licensee shall establish removable contamination action levels for the surveys required by subdivision e and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by subdivisions a, b, and e for ~~two~~ three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in ~~millirems-[microsieverts]~~ microsieverts [millirems] per hour or the removable contamination in each area expressed in ~~disintegrations---per---minute [becquerels]~~ becquerels [disintegrations per minute] per one hundred square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

~~12.~~ 13. **Release of ~~patients~~ individuals containing radiopharmaceuticals or permanent implants.**

a. ~~A--licensee-may-not-authorize-release-from-confinement-for medical----care-----any-----patient-----administered-----a radiopharmaceutical---until---either:~~ The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts [0.5 rem].

~~(1)--The--dose--rate--from--the--patient-is-less-than-five millirems-[50--microsieverts]-per-hour-at-a--distance of-one-meter;-or~~

~~(2)--The--activity--in--the--patient--is--less-than-thirty millicuries-[1.11-gigabecquerels].~~

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one

millisievert [0.1 rem]. If the dose to a breast-feeding infant or child could exceed one millisievert [0.1 rem] assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than twenty-five hundredths at one meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

d. The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts [0.5 rem].

~~b.--A--licensee--shall--not-authorize-release-from-confinement for-medical-care--any--patient--administered--a--permanent implant--until-the-dose-rate-from-the-patient-is-less-than five-millirems-[50--microsieverts]-per-hour-at-a--distance of-one-meter.~~

~~13.~~ 14. **Mobile nuclear medicine service technical requirements.** A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in paragraph 1 of subdivision b of subsection 2, subdivisions d and e of subsection 2, subdivision d of subsection 3, and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed~~.~~; and

f. Retain a record of each survey required by subdivision e for ~~two~~ three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in ~~millirems--[microsieverts]~~ microsieverts [millirems] per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

~~14.~~ 15. **Storage of volatiles and gases.**

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

~~15.~~ 16. **Decay-in-storage.**

a. A licensee may hold radioactive material for decay-in-storage before disposal in ordinary trash if the licensee:

(1) Holds radioactive material for decay a minimum of ten half-lives;

(2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with subdivision a, the licensee shall retain a record of each disposal for ~~two~~ three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

History: Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-06. Specific requirements for the use of ~~radiopharmaceuticals~~ unsealed radioactive material for uptake, dilution, or excretion studies.

1. **Use of ~~radiopharmaceuticals~~ unsealed radioactive material for uptake, dilution, or excretion studies.**

a. ~~A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:~~

~~(1) Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate.~~

~~(2) Iodine-125 as sodium iodide or iodinated human serum albumin (IHSA).~~

~~(3) Cobalt-57 as labeled cyanocobalamin.~~

~~(4) Cobalt-58 as labeled cyanocobalamin.~~

~~(5) Cobalt-60 as labeled cyanocobalamin.~~

~~(6) Chromium-51 as sodium chromate or labeled human serum albumin.~~

~~(7) Iron-59 as citrate.~~

~~(8) Technetium-99m as pertechnetate.~~

~~(9)--Any-radioactive-material-in-a-radiopharmaceutical-for a-diagnostic-use-involving--measurements--of--uptake, dilution,--or--excretion--for-which-the-food-and-drug administration-has--accepted--a--"notice--of--claimed investigational--exemption--for--a-new-drug"-(IND)-or approved-a-"new-drug-application"-(NDA).~~ A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that is either:

(1) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements; or

(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection 4 of section 33-10-07-12, or an individual under the supervision of either as specified in subsection 5 of section 33-10-07-04.

b. A licensee using a radiopharmaceutical specified in this subsection for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

2. **Possession of survey instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range ~~one-tenth---millirem---[1.0---microsievert]~~ one microsievert [0.1 millirem] per hour to ~~fifty-millirems-[500-microsieverts]~~ five hundred microsieverts [50 millirems] per hour. The instrument shall be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-07. Specific requirements for the use of ~~radiopharmaceuticals,-generators,-and-reagent-kits~~ unsealed radioactive material for imaging and localization studies.

1. **Use of ~~radiopharmaceuticals,--generators,--and--reagent-kits~~ unsealed radioactive material for imaging and localization studies.** A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

a. A--licensee--may--use--the-following-radiopharmaceuticals, generators,-and-reagent-kits-for-imaging-and--localization studies:

(1)--Molybdenum-99/technetium-99m---generators---for---the elution---or---extraction---of---technetium-99m----as pertechnetate.

(2)--Technetium-99m-as-pertechnetate.

(3)--Prepared--radiopharmaceuticals--and--reagent-kits-for the--preparation--of--the--following---technetium-99m labeled-radiopharmaceuticals:

(a)--Sulfur-colloid;

(b)--Pentetate-sodium;

(c)--Human-serum-albumin-microspheres;

(d)--Polyphosphate;

(e)--Macroaggregated-human-serum-albumin;

(f)--Etidronate-sodium;

(g)--Stannous-pyrophosphate;

(h)--Human-serum-albumin;

(i)--Medronate-sodium;

(j)--Gluceptate-sodium;

(k)--Oxidronate-sodium;

(l)--Disofenin;-and

(m)--Succimer.

(4)--Iodine-131--as--sodium--iodide,-iodinated-human-serum albumin,--macroaggregated---iodinated---human---serum albumin,--colloidal-(macroaggregated)-iodinated-human serum-albumin,-rose-bengal,-or-sodium--iodohippurate.

(5)--Iodine-125-as-sodium-iodide-or-fibrinogen.

(6)--Chromium-51-as-human-serum-albumin.

(7)--Gold-198-in-colloidal-form.

(8)--Mercury-197-as-chlormerodrin.

~~(9)--Selenium-75-as-selenomethionine.~~

~~(10)--Strontium-85-as-nitrate.~~

~~(11)--Ytterbium-169-as-pentetate-sodium.~~

~~(12)--Gallium-67-as-citrate.~~

~~(13)--Indium-111-as-chloride-or-DTPA.~~

(14) Tin-113/indium-113m generators for the elution of indium-113m as chloride.

~~(15)--Yttrium-87/strontium-87m--generators--for-the-elution of-strontium-87m.~~

~~(16)--Thallium-201-as-chloride.~~

~~(17)--Iodine-123-as-sodium-iodide-or-iodohippurate.~~

~~(18)--Any----radioactive----material----in---a---diagnostic radiopharmaceutical,-except-aerosol-or-gaseous--form, or--any--generator-or-reagent-kit-for-preparation-and diagnostic-use-of--a--radiopharmaceutical--containing radioactive--material--for--which--the--food-and-drug administration-has--accepted--a--"notice--of--claimed investigational--exemption--for--a--new--drug"-(IND), approved-a-"product-licensing--agreement"--(PLA),--or approved--a--"new--drug-application"-(NDA).~~ Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements; or

b. ~~A---licensee---using---radiopharmaceuticals--specified--in subdivision-a-for-clinical-proceedures--shall--comply--with the--product--label--or--package-insert-regarding-physical form,-route-of-administration,-and-dosage-range.~~ Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection 4 of section 33-10-07-12, or an individual under the supervision of either as specified in subsection 5 of section 33-10-07-04.

~~c.--A--licensee--shall--elute--generators--in--compliance-with subseetion-2-and-prepare-radiopharmaceuticals-from-kits-in accordance-with-the-manufacturer's-instructions.~~

~~d.--Technetium-99m--pentetate--as-an-aerosol-for-lung-function studies--is---not---subject---to---the---restrictions---in subdivision-b.~~

e.--Provided---the--conditions--of--subsection-3--are--met,--a licensee-shall-use-radioactive-aerosols-or-gases--only--if specific--application--is--made--to--and--approved--by-the department.

2. **Permissible molybdenum-99 concentration.**

   a. A licensee may not administer a radiopharmaceutical containing more than fifteen hundredths ~~microcurie~~ kilobecquerel of molybdenum-99 per ~~millicurie~~ megabecquerel of technetium-99m [0.15 ~~kilobecquerel~~ microcurie of molybdenum-99 per ~~megabecquerel~~ millicurie of technetium-99m].

   b. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

   c. A licensee who must measure molybdenum concentration shall retain a record of each measurement for ~~two~~ three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in ~~millicuries-[megabecquerels]~~ megabecquerels [millicuries], the measured activity of molybdenum expressed in ~~microcuries-[kilobecquerels]~~ kilobecquerels [microcuries], the ratio of the measures expressed as ~~microcuries--of--molybdenum--per--millicurie-of-technetium~~ [kilobecquerels of molybdenum per megabecquerel of technetium] [microcuries of molybdenum per millicurie of technitium], the date of the test, and the initials of the individual who performed the test.

   d. A licensee shall report immediately to the department each occurrence of molybdenum-99 concentration exceeding the limits specified in subdivision a.

3. **Control of aerosols and gases.**

   a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by sections 33-10-04.1-06 and 33-10-04.1-07.

   b. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

   c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in appendix B of chapter 33-10-04.1. The calculation must be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in subdivision d at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements must be maintained for ~~two~~ three years.

g. A copy of the calculations required in subdivision d must be recorded and retained for the duration of the license.

4. **Possession of survey instruments.** A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of ~~one-tenth millirem--[1-microsievert]~~ one microsievert [0.1 millirem] per hour to ~~fifty--millirems--[500--microsieverts]~~ five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one-millirem-[10-microsieverts]~~ ten microsieverts [1 millirem] per hour to ~~one-thousand--millirems [10--millisieverts]~~ ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.

History: Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-08. Specific requirements for the use of ~~radiopharmaceuticals--for--therapy~~ unsealed radioactive material for therapeutic administration.

1. **Use of ~~radiopharmaceuticals-for-therapy~~ unsealed radioactive material for therapeutic administration.** ~~A-licensee--may--use the--following--prepared--radiopharmaceuticals:~~ A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

a. ~~Iodine-131--as--iodide--for--treatment-of-hyperthyroidism, cardiac-dysfunction,-and-thyroid-carcinoma.~~ Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, subdivision i of subsection 5 of section 33-10-03-05, or equivalent agreement state or licensing state requirements; or

b. ~~Phosphorus-32---as--soluble--phosphate--for--treatment--of polycythemia--vera,---leukemia,---and---bone---metastases.~~ Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in subsection 4 of section 33-10-07-12, or an individual under the supervision of either as specified in subsection 5 of section 33-10-07-04.

~~c.--Phosphorus-32---as---colloidal---chromic---phosphate---for intracavitary-treatment-of-malignant-effusions.~~

~~d.--Gold-198---as---colloid--for--intracavitary--treatment--of malignant-effusions.~~

~~e.--Any--radioactive-material-in-a-radiopharmaceutical-and-for a--therapeutic--use--for---which---the---food---and---drug administration---has---accepted---a---"notice--of--claimed investigational--exemption--for--a--new--drug"--(IND),--or approved--a--"new--drug--application"-(NDA).--The-licensee shall--comply--with--the---package---insert---instructions regarding-indications-and-method-of-administration.~~

2. **Safety instruction.**

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy. Refresher training must be provided at intervals not to exceed one year.

b. To satisfy subdivision a, the instruction must describe the licensee's procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the radiation safety officer or authorized user in case of the patient's or the human research subject's death or medical emergency~~;-and~~.

~~(6)--Chapter-33-10-10-training-requirements.~~

c. A licensee shall keep a record of individuals receiving instruction required by subdivision a, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record must be maintained for inspection by the department for ~~two~~ three years.

3. **Safety precautions.**

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with subsection ~~12~~ 13 of section 33-10-07-05, a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under eighteen years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of chapter 33-10-04.1 and retain for ~~two~~ three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) ~~Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as is reasonably achievable before authorizing release of the patient;~~

~~(7)~~ Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than two hundred disintegrations per minute [3.33 becquerels] per one hundred square centimeters; and

~~(8)~~ (7) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by subdivision a of subsection 7 of section 33-10-04.1-15 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or the human research subject dies or has a medical emergency.

4. **Possession of survey instruments.** A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range ~~one-tenth millirem--[1-microsievert]~~ one microsievert [0.1 millirem] per hour to ~~fifty--millirems--[500--microsieverts]~~ five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one-millirem-[10-microsieverts]~~ ten microsieverts [1 millirem] per hour to ~~one-thousand--millirems [10--millisieverts]~~ ten millisieverts [1000 millirems] per hour. The instrument must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.

History: Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-09. Specific requirements for the use of sealed sources for diagnosis.

1. **Use of sealed sources for diagnosis.** A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

   a. Iodine-125 as a sealed source in a device for bone mineral analysis;

b. Americium-241 as a sealed source in a device for bone mineral analysis;

c. Gadolinium-153 as a sealed source in a device for bone mineral analysis; and

d. Iodine-125 as a sealed source in a portable device for imaging.

2. **Availability of survey instrument.** A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range ~~one-tenth--millirem--{1--microsievert}~~ one microsievert [0.1 millirem] per hour to ~~fifty-millirems--{500 microsieverts}~~ five hundred millisieverts [50 millirems] per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one-millirem {10-microsieverts}~~ ten microsieverts [1 millirem] per hour to ~~--one--thousand-millirems-{10-millisieverts}~~ ten millisieverts [1000 millirems] per hour. The instrument must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-10. Specific requirements for the use of sources for brachytherapy.

1. **Use of sources for brachytherapy.** A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

   a. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

   b. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

   c. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

   d. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

   e. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

f. Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;

g. Radon-222 as seeds for interstitial treatment of cancer;

h. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

i. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

2. **Safety instruction.**

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training must be provided at intervals not to exceed one year.

b. To satisfy subdivision a, the instruction must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control;

(5) Procedures for notification of the radiation safety officer or authorized user if the patient or the human research subject dies or has a medical emergency; and.

~~(6)--Chapter-33-10-10-training-requirements.~~

c. A licensee shall maintain a record of individuals receiving instruction required by subdivision a, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for ~~two~~ three years.

3. **Safety precautions.**

a. For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to subection 13 of section 33-10-07-05, a licensee shall:

(1) Not place the patient or the human research subject in the same room with a patient or human research subject who is not receiving radiation therapy ~~unless the licensee can demonstrate compliance with the requirement of subdivision a of subsection 1 of section 33-10-04.1-07 at a distance of one meter from the implant~~;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under eighteen years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with chapter 33-10-04.1 and retain for ~~two~~ three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in ~~millirems [microsieverts]~~ microsieverts [millirems] per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

~~(5) Provide the patient with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.~~

b. A licensee shall notify the radiation safety officer or authorized user immediately if the patient or the human research subject dies or has a medical emergency.

4. **Brachytherapy sources inventory.**

a. ~~Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify~~ Promptly after removing brachytherapy sources from a patient or human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, ~~the room number of use and patient's name~~ the patient's or the human research subject's name and room number, the time and date ~~they~~ the brachytherapy sources were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, ~~the room number of use and patient's name~~ the patient's or the human research subject's name and room number, the time and date ~~they~~ the brachytherapy sources were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in subdivisions b and c for ~~two~~ three years.

5. **Release of patients** or human research subjects **treated with temporary implants.**

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with subdivision a for ~~two~~ three years. Each record must include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or

human research subject expressed as ~~millirems [microsieverts]~~ microsieverts [millirems] per hour and measured within one meter from the patient or human research subject, and the initials of the individual who made the survey.

6. **Possession of survey instruments.** A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range ~~one-tenth--millirem--[1 microsievert]~~ one microsievert [0.1 millirem] per hour to ~~fifty-millirems-[500-microsieverts]~~ five hundred microsieverts [50 millirems] per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one--millirem--[10--microsieverts]~~ ten microsieverts [1 millirem] per hour to ~~one---thousand---millirems---[10 millisieverts]~~ ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.

History: Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-11. Specific requirements for the use of a sealed source in teletherapy.

1. **Use of a sealed source in a teletherapy unit.** A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

2. **Maintenance and repair restrictions.** Only a person specifically licensed by the department, the United States nuclear regulatory commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

3. **Amendments.** In addition to the requirements specified in section 33-10-07-03.1, a licensee shall apply for and receive a license amendment before:

   a. Making any change in the treatment room shielding;

   b. Making any change in the location of the teletherapy unit within the treatment room;

c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

d. Relocating the teletherapy unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

4. **Safety instruction.**

a. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and

(3) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.

b. A licensee shall provide instruction in the topics identified in subdivision a to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

c. A licensee shall maintain a record of individuals receiving instruction required by subdivision b, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for ~~two~~ three years.

5. **Doors, interlocks, and warning systems.**

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

c. A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

6. **Possession of survey instrument.** A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range ~~one-tenth millirem--[1-microsievert]~~ one microsievert [0.1 millirem] per hour to ~~fifty--millirems--[500--microsieverts]~~ five hundred microsieverts [50 millirems] per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~one---millirem---[10--microsieverts]~~ ten microsieverts [1 millirem] per hour to ~~one-thousand--millirems [10--millisieverts]~~ ten millisieverts [1000 millirems] per hour. The instruments must be operable and calibrated in accordance with subsection 3 of section 33-10-07-05.

7. **Radiation monitoring device.**

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.

c. Each radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by subdivision d for ~~two~~ three years. The record must include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subdivision e.

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

8. **Viewing system.** A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

9. **Dosimetry equipment.**

a. A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(1) The system must have been calibrated by the national institute of standards and technology or by a calibration laboratory accredited by the American association of physicists in medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the national institute of standards and technology or by a calibration laboratory accredited by the American association of physicists in medicine. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the American association of physicists in medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to

change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision a. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system must be the same system used to meet the requirement in subdivision a.

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subdivisions a and b the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American association of physicists in medicine.

10. **Full calibration measurements.**

a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

b. To satisfy the requirement of subdivision a, full calibration measurements must include determination of:

(1) The output within three percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy, constancy, and linearity;

(5) "On-off" error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

c. A licensee shall use the dosimetry system described in subsection 9 to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 1 of subdivision b may then be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by subsection 1 in accordance with either the procedures recommended by the scientific committee on radiation dosimetry of the American association of physicists in medicine that are described in Physics in Medicine and Biology vol. 16, no. 3, 1971, pp. 379-396, or by task group 21 of the radiation therapy committee of the American association of physicists in medicine that are described in Medical Physics vol. 10, no. 6, 1983, pp. 741-771, and vol. 11, no. 2, 1984, p. 213.

e. A licensee shall correct mathematically the outputs determined in paragraph 1 of subdivision b for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.

f. Full calibration measurements required by subdivision a and physical decay corrections required by subdivision e must be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by

the United States nuclear regulatory commission or an agreement state to perform such services.

g. A licensee shall maintain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

11. **Periodic spot checks.**

a. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.

b. To satisfy the requirement of subdivision a, spot checks must include determination of:

(1) Timer constancy and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions; and

(6) The difference between the measurement made in paragraph 5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

c. A licensee shall use the dosimetry system described in subsection 9 to make the spot check required in paragraph 5 of subdivision b.

d. A licensee shall perform spot checks required by subdivision a in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

e. A licensee shall have the teletherapy physicist review the results of each output spot check within fifteen days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for ~~two~~ three years.

f. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.

g. To satisfy the requirement of subdivision f, safety spot checks shall assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

h. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee may use the unit until the interlock system is repaired unless specifically authorized by the department.

i. A licensee shall promptly repair any system identified in subdivision g that is not operating properly. The teletherapy unit may not be used until all repairs are completed.

j. A licensee shall maintain a record of each spot check required by subdivisions a and f for ~~two~~ three years. The record must include the date of the spot check, the

manufacturer's name, model number, and serial number for both the teletherapy unit, and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

12. **Radiation surveys for teletherapy facilities.**

a. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by subsection 3, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with subsection 3 of section 33-10-07-05 to verify that:

(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed ~~ten--millirems--[100 microsieverts]~~ one hundred microsieverts [10 millirems] per hour and ~~two---millirems---[20 microsieverts]~~ twenty microsieverts [2 millirems] per hour, respectively; and

(2) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in subsection 1 of section 33-10-04.1-06; and

(b) Radiation levels in unrestricted areas do not exceed the limits specified in subsection 1 of section 33-10-04.1-07.

b. If the results of the surveys required in subdivision a indicate any radiation levels in excess of the respective

limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(2) Until the licensee has received a specific exemption from the department.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in ~~millirems [microsieverts]~~ microsieverts [millirems] per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

13. **Safety spot checks for teletherapy facilities.**

a. A licensee shall promptly check all systems listed in subdivision g of subsection 11 for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by subsection 3.

b. If the results of the safety spot checks required in subdivision a indicate the malfunction of any system specified in subsection 11, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for ~~two~~ three years. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

14. **Modification of teletherapy unit or room before beginning a treatment program.** If the survey required by subsection 12 indicates that an individual in an unrestricted area may be

exposed to levels of radiation greater than those permitted by subsection 1 of section 33-10-04.1-07, before beginning the treatment program the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with subsection 1 of section 33-10-04.1-07;

b. Perform the survey required by subsection 12 again; and

c. Include in the report required by subsection 15 the results of the initial survey, a description of the modification made to comply with subdivision a, and the results of the second survey; or

d. Request and receive a license amendment under subdivision c of subsection 1 of section 33-10-04.1-07 that authorizes radiation levels in unrestricted areas greater than those permitted by subdivision a of subsection 1 of section 33-10-04.1-07.

15. **Reports of teletherapy surveys, checks, tests, and measurements.** A licensee shall furnish a copy of the records required in subsections 12, 13, and 14 and the output from the teletherapy source expressed as ~~rems--[sieverts]~~ sieverts [rems] per hour at one meter from the source as determined during the full calibration required in subsection 10 to the department within thirty days following completion of the action that initiated the record requirement.

16. **Five-year inspection.**

a. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

b. This inspection and servicing may only be performed by persons specifically licensed to do so by the department, an agreement state, or the United States nuclear regulatory commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

History: Effective June 1, 1992; amended effective March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-07-12. Specific requirements for training.

1. **Radiation safety officer.** Except as provided in subsection 2 an individual fulfilling the responsibilities of the radiation safety officer as provided in subsection 2 of section 33-10-07-04 shall:

   a. Be certified by the:

      (1) American board of health physics in comprehensive health physics;

      (2) American board of radiology ~~in radiological physics, therapeutic radiological physics, or medical - nuclear physics~~;

      (3) American board of nuclear medicine;

      (4) American board of science in nuclear medicine; ~~or~~

      (5) Board of pharmaceutical specialities in nuclear pharmacy ~~or science~~; ~~or~~

      (6) American board of medical physics in radiation oncology;

      (7) Royal college of physicians and surgeons of Canada in nuclear medicine;

      (8) American osteopathic board of radiology; or

      (9) American osteopathic board of nuclear medicine; or

   b. Have had two hundred hours of classroom and laboratory training as follows:

      (1) Radiation physics and instrumentation;

      (2) Radiation protection;

      (3) Mathematics pertaining to the use and measurement of radioactivity;

      (4) Radiation biology;

      (5) Radiopharmaceutical chemistry; and

(6) One year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer by the department, an agreement state, licensing state, or United States nuclear regulatory commission license that authorizes the medical use of radioactive material; or

c. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.

2. **Training for experienced radiation safety officer.** An individual identified as a radiation safety officer by the department, agreement state, licensing state, or United States nuclear regulatory commission license on October 1, 1986, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of subsection 1.

3. **Training for uptake, dilution, or excretion studies.** Except as provided in subsections 11 and 12, the licensee shall require the authorized user of a radiopharmaceutical listed in section 33-10-07-06 to be a physician who:

a. Is certified in:

(1) Nuclear medicine by the American board of nuclear medicine;

(2) Diagnostic radiology by the American board of radiology;

(3) Diagnostic radiology or radiology ~~within the previous five years~~ by the American osteopathic board of radiology; ~~or~~

(4) Nuclear medicine by the American osteopathic board of nuclear medicine; or

(5) Nuclear medicine by the royal college of physicians and surgeons of Canada; or

b. Has completed forty hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and twenty hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, forty hours of classroom and laboratory instruction must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiation biology; and

(e) Radiopharmaceutical chemistry.

(2) To satisfy the requirement for twenty hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(a) Examining patients or human research subjects and reviewing ~~the patients'~~ their case histories to determine ~~the patients'~~ their suitability for radionuclide diagnosis, limitations, or contraindications;

(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(c) Administering dosages to patients or human research subjects and using syringe radiation shields;

(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and

(e) Patient or human research subject followup; or

c. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subdivision b.

4. **Training for imaging and localization studies.** Except as provided in subsections 11 and 12, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in section 33-10-07-07 to be a physician who:

a. Is certified in:

(1) Nuclear medicine by the American board of nuclear medicine;

(2) Diagnostic radiology by the American board of radiology;

(3) Diagnostic radiology or radiology ~~within the previous five years~~ by the American osteopathic board of radiology; ~~or~~

(4) Nuclear medicine by the American osteopathic board of nuclear medicine; or

(5) Nuclear medicine by the royal college of physicians and surgeons of Canada; or

b. Has completed two hundred hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, five hundred hours of supervised work experience, and five hundred hours of supervised clinical experience:

(1) To satisfy the basic instruction requirement, two hundred hours of classroom and laboratory training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiopharmaceutical chemistry; and

(e) Radiation biology.

(2) To satisfy the requirement for five hundred hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and must include:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(c) Calculating and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent the misadministration of radioactive material;

(e) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(3) To satisfy the requirement for five hundred hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and must include:

(a) Examining patients or human research subjects and reviewing ~~the patients'~~ their case histories to determine ~~the patients'~~ their suitability for radionuclide diagnosis, limitations, or contraindications;

(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(c) Administering dosages to patients or human research subjects and using syringe radiation shields;

(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and

(e) Patient or human research subject followup; or

c. Has successfully completed a six-month training program in nuclear medicine that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subdivision b.

5. **Training for therapeutic use of ~~radiopharmaceuticals~~** unsealed radioactive material. Except as provided in subsection 11, the licensee shall require the authorized user of a radiopharmaceutical listed in section 33-10-07-08 for therapy to be a physician who:

a. Is certified by:

(1) The American board of nuclear medicine; ~~or~~

(2) The American board of radiology in radiology, therapeutic radiology, or radiation oncology; ~~or~~

(3) Royal college of physicians and surgeons of Canada in nuclear medicine; or

(4) The American osteopathic board of radiology after 1984; or

b. Has completed eighty hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

(1) To satisfy the requirement for instruction, eighty hours of classroom and laboratory training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(a) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

(b) Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

(c) Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and

(d) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals.

6. **Training for therapeutic use of brachytherapy sources.** Except as provided in subsection 11, the licensee shall require the authorized user using a brachytherapy source specified in section 33-10-07-10 for therapy to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American board of radiology;

(2) Radiation oncology by the American osteopathic board of radiology;

(3) Radiology, with a specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or

(4) Therapeutic radiology by the Canadian royal college of physicians and surgeons; or

b. Is in the active practice of therapeutic radiology, has completed two hundred hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and five hundred hours of supervised work experience and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, two hundred hours of classroom and laboratory training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology.

(2) To satisfy the requirement for five hundred hours of supervised work experience, training must be under the supervision of an authorized user at a medical institution and must include:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing sealed sources;

(d) Using administrative controls to prevent the misadministration of radioactive material; and

(e) Using emergency procedures to control radioactive material.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the residency review committee for radiology of the accreditation council for graduate medical education or the committee on postdoctoral training of the

American osteopathic association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience must include:

(a) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(b) Selecting the proper brachytherapy sources, dose, and method of administration;

(c) Calculating the dose; and

(d) Postadministration followup and review of case histories in collaboration with the authorized user.

7. **Training for ophthalmic use of strontium-90.** Except as provided in subsection 11, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is certified in radiology, therapeutic radiology, or radiation oncology by the American board of radiology; or

b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed twenty-four hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at a medical institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and

(d) Followup and review of each individual's case history.

8. **Training for use of sealed sources for diagnosis.** Except as provided in subsection 11, the licensee shall require the authorized user using a sealed source in a device specified in section 33-10-07-09 to be a physician, dentist, or podiatrist who:

a. Is certified in:

(1) Radiology, diagnostic radiology ~~with---special competence---in---nuclear---radiology~~, therapeutic radiology, or radiation oncology by the American board of radiology;

(2) Nuclear medicine by the American board of nuclear medicine; ~~or~~

(3) Diagnostic radiology or radiology by the American osteopathic board of radiology; or

(4) Nuclear medicine by the royal college of physicians and surgeons of Canada; or

b. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training must include:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology; and

(3) Radiation protection and training in the use of the device for the purposes authorized by the license.

9. **Training for teletherapy.** Except as provided in subsection 11, the licensee shall require the authorized user of a sealed source specified in section 33-10-07-11 to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American board of radiology;

(2) Radiation oncology by the American osteopathic board of radiology;

(3) Radiology, with specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or

(4) Therapeutic radiology by the Canadian royal college of physicians and surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed two hundred hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, five hundred hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and shall include:

(a) Review of the full calibration measurements and periodic spot checks;

(b) Preparing treatment plans and calculating treatment times;

(c) Using administrative controls to prevent misadministrations;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(e) Checking and using survey meters.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the residency review committee for radiology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American osteopathic association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience must include:

(a) Examining individuals and reviewing the individuals' case histories to determine the individuals' suitability for teletherapy treatment, and any limitations or contraindications;

(b) Selecting the proper dose and how it is to be administered;

(c) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' <u>or human research subject's</u> progress and consideration of the need to modify originally prescribed doses as warranted by patients' <u>or human research subject's</u> reaction to radiation; and

(d) Postadministration followup and review of case histories.

10. **Training for teletherapy physicist.** The licensee shall require the teletherapy physicist to:

a. Be certified by the American board of radiology in:

(1) Therapeutic radiological physics;

(2) Roentgen-ray and gamma-ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

b. <u>Be certified by the American board of medical physics in radiation oncology physics; or</u>

<u>c.</u> Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy

physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in subsection ~~6~~ 7 of section 33-10-07-05 and subsections 10, 11, and 12 of section 33-10-07-11 under the supervision of a teletherapy physicist during the year of work experience.

11. **Training for experienced authorized users.** Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a department, United States nuclear regulatory commission, agreement state, or licensing state license on April 1, 1987, who perform only those methods of use for which the practitioners were authorized on that date need not comply with the training requirements of this section.

12. **Physician training in a three-month program.** A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the accreditation council for graduate medical education and has successfully completed the program, is exempted from the requirements of subsections 3 and 4.

13. **Recentness of training.** The training and experience specified in this section shall have been obtained within the ~~five~~ seven years preceding the date of application or the individual shall have had continuing education and applicable experience since the required training and experience was completed.

14. **Training for treatment of hyperthyroidism.** Except as provided in subsection 11, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radiosisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

    a. Eighty hours of classroom and laboratory training that includes:

        (1) Radiation physics and instrumentation;

        (2) Radiation protection;

        (3) Mathematics pertaining to the use and measurement of radioactivity; and

        (4) Radiation biology; and

    b. Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for

diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.

15. Training for an authorized nuclear pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Has current board certification as a nuclear pharmacist by the board of pharmaceutical specialties, or

b. (1) Has completed seven hundred hours in a structured educational program consisting of both:

(a) Didactic training in the following areas:

[1] Radiation physics and instrumentation;

[2] Radiation protection;

[3] Mathematics pertaining to the use and measurement of radioactivity;

[4] Chemistry of radioactive material for medical use; and

[5] Radiation biology; and

(b) Supervised experience in a nuclear pharmacy involving the following:

[1] Shipping, receiving, and performing related radiation surveys;

[2] Using and performing checks for proper operation of dose calibrators, survey meters, and if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

[3] Calculating, assaying, and safely preparing dosages for patients or human research subjects;

[4] Using administrative controls to avoid mistakes in the administration of radioactive material;

[5] Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist that the

above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

16. Training for experienced nuclear pharmacists. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. The pharmacist who has completed a structured educational program as specified in paragraph 1 of subdivision b of subsection 15 before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (paragraph 2 of subdivision b of subsection 15) and recentness of training (subsection 13) to qualify as an authorized nuclear pharmacist.

History: Effective June 1, 1992; amended effective March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-08-03. Equipment requirements.

1. **Safety device.** A device which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the department for an exemption from the requirement of a safety device. Such application shall include:

   a. A description of the various safety devices that have been evaluated.

   b. The reason each of these devices cannot be used.

   c. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

2. **Warning devices.**

   a. Open-beam configurations shall be provided with a readily discernible indication of:

      (1) X-ray tube (ON-OFF) status located near the radiation source housing, if the primary beam is controlled in this manner.

      (2) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

   b. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, must be located:

      (1) Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized.

      (2) In the case of a radioactive source, near any switch that opens a housing shutter and must be illuminated only when the shutter is open.

   c. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after August 1, 1979, warning devices shall have fail-safe characteristics.

3. **Ports.** Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

4. **Labeling.** All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

   a. "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the X-ray source housing; and

   b. "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

   c. "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with subsection 4 of section 33-10-04.1-13 if the radiation source is a radionuclide.

5. **Shutters.** On open-beam configurations installed after August 1, 1979, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

6. **Warning lights.**

   a. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

      (1) Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

      (2) In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

   b. On equipment installed after August 1, 1979, warning lights shall have fail-safe characteristics.

7. **Radiation source housing.** Each radiation source housing is subject to the following requirements:

   a. Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

   b. Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all

shutters closed, the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of ~~two-and-one-half-millirems {0.25-millisieverts}~~ twenty-five hundredths millisieverts [2.5 millirems] in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

8. **Generator cabinet.** Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of ~~one-quarter--millirem--{2.5--microsieverts}~~ two and one-half microsieverts [0.25 millirem] in one hour.

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

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 ~~engaged in licensed activities which involve exposure to radiation or to radioactive material, or both~~ likely to receive in a year an occupational dose in excess of one millisievert [100 millirem]:

(1) Must be kept informed of the storage, transfer, or use of ~~radioactive material or of~~ sources of radiation ~~in the licensee's facility~~.

(2) Must be instructed in the health protection problems associated with exposure to ~~such~~ 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 in, and ~~instructed~~ 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 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 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 as to the radiation exposure reports which workers must be furnished 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 ~~advise~~ furnish to each worker annually~~,-in--writing,~~ 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 ~~radiation from--radioactive--material--licensed--by,--or---radiation machines---registered--with--the--department;~~ 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 ~~subsection 3 of~~ 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 ~~report on the individual's exposure data included therein~~ 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, 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.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-11

33-10-11-04. 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, except:

   ~~a. Licensees with the anniversary date of the license expiration date between May 1, 1995, and December 31, 1995, will be assessed an annual fee on the anniversary date of the license expiration date prorated to January 1, 1996. These licensees will then pay a full annual fee on January 1, 1996, and every year thereafter.~~

   ~~b. Licensees with the anniversary date of the license expiration date between January 1, 1996, and April 30, 1996, will not be assessed an annual fee on January 1, 1996. These licensees will be assessed an annual fee on the anniversary date of the license expiration date prorated to January 1, 1997. These licensees will then pay a full annual fee on January 1, 1997, and every year thereafter~~ 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 hundred dollars for industrial radiography or one thousand dollars for well logging.

   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
~~and Consolidated Laboratories~~
Division of Environmental Engineering
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.
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 of Materials Licenses and Types of Fees	Fee ($)
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	Full Cost
Inspection (nonroutine)	Full Cost
Annual Fee	71,450
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI):	
(Regulated by NRC)	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	125
Inspection (nonroutine)	435
Annual Fee	600
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	75
Inspection (nonroutine)	265
Annual Fee	730
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	Full Cost
Inspection (nonroutine)	Full Cost
Annual Fee	371,295

B. Licenses for possession and use of source material for shielding:	
Amendment	40
Inspection (nonroutine)	115
Annual Fee	210
C. All other source material licenses:	
Amendment	150
Inspection (nonroutine)	500
Annual Fee	1530
3. Byproduct material and 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	75
Inspection (nonroutine)	1050
Annual Fee	4400
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	185
Inspection (nonroutine)	665
Annual Fee	2000
C. Licenses issued pursuant to chapter 33-10-03 authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material or naturally occurring or accelerator-produced radioactive material:	
Amendment	150
Inspection (nonroutine)	635
Annual Fee	4000
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	105
Inspection (nonroutine)	400
Annual Fee	1750

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	115
	Inspection (nonroutine)	230
	Annual Fee	810
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	115
	Inspection (nonroutine)	425
	Annual Fee	1500
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	155
	Inspection (nonroutine)	465
	Annual Fee	7150
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	85
	Inspection (nonroutine)	345
	Annual Fee	2265
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	115
	Inspection (nonroutine)	230
	Annual Fee	3410

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 Inspection (nonroutine) Annual Fee	 130 345 2200
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 Inspection (nonroutine) Annual Fee	 95 345 2030
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 Inspection (nonroutine) Annual Fee	 165 400 1200
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 Inspection (nonroutine) Annual Fee	 210 310 1700
N.	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration and/or leak testing services only are subject to the fees specified in fee Category 3P, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C: Amendment Inspection (nonroutine) Annual Fee	 135 345 2000

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 radiography operations:	
	Amendment	165
	Inspection (nonroutine)	835
	Annual Fee	2700
P.	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except those in Categories 4A through 9D:	
	Amendment	125
	Inspection (nonroutine)	600
	Annual Fee	770
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:	Full Cost
	Amendment	Full Cost
	Inspection (nonroutine)	43,380
	Annual Fee	
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	65
	Inspection (nonroutine)	700
	Annual Fee	5465
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:	75
	Amendment	700
	Inspection (nonroutine)	2500
	Annual Fee	

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:	180
	Amendment	400
	Inspection (nonroutine)	2300
	Annual Fee	
B.	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies:	Full Cost
	Amendment	335
	Inspection (nonroutine)	5130
	Annual Fee	
6.	Nuclear laundries:	
A.	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:	115
	Amendment	635
	Inspection (nonroutine)	2400
	Annual Fee	
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:	145
	Amendment	635
	Inspection (nonroutine)	5630
	Annual Fee	
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:	120
	Amendment	600
	Inspection (nonroutine)	5800
	Annual Fee	

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, or special nuclear material in sealed sources contained in teletherapy devices:	
	Amendment	145
	Inspection (nonroutine)	500
	Annual Fee	1965
8.	Civil defense:	
A.	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	105
	Inspection (nonroutine)	230
	Annual Fee	700
9.	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	400
	Inspection (nonroutine)	Full Cost
	Annual Fee	3200
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	195
	Inspection (nonroutine)	Full Cost
	Annual Fee	1630
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	75
	Inspection (nonroutine)	Full Cost
	Annual Fee	700

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 Inspection (nonroutine) Annual Fee	 40 Full Cost 330
10. Transportation of radioactive material: (Regulated by NRC)	N/A
11. Review of standardized spent fuel facilities: (Regulated by NRC)	N/A
12. Special projects:	Full Cost
13. A. Spent fuel storage cask Certificate of Compliance: (Regulated by NRC)	N/A
B. Inspections related to spent fuel storage cast Certificate of Compliance: (Regulated by NRC)	N/A
C. Inspections related to storage of spent fuel under of this chapter: (Regulated by NRC)	N/A
14. Byproduct, naturally occurring or accelerator-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 Inspection (nonroutine) Annual Fee	 Full Cost Full Cost Full Cost
15. Import and Export licenses: (Regulated by NRC)	N/A
16. Reciprocity: Other agreement state and NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03. Application fee (due 3 days prior to entry into State) Inspections (nonroutine)	 Fees as specified in annual fees for license type Fees as specified under inspection fees for license type
17. Demonstration and sales of devices containing radioactive materials.	160 per year

18.	Radiation training courses.	160 per year
19.	Decontamination services.	800 per year
20.	Installation, removal, repair and servicing of devices containing radioactive materials.	760 per year
21.	Multiple offices: Add the following fees per additional office location: Amendment Inspection (nonroutine) Annual Fee	 same as base fee same as base fee 25% of base fee
22.	Administrative amendment (limited to the following amendment requests: - Corporate name change - Minor O&E manual changes (industrial sources) - Filing of training certificates (gauge users)	$85
23.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Full Cost
24.	Certificate - in vitro testing with radioactive material under general license. Application - 3 year certificate.	$100

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

CHAPTER 33-10-12

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 ~~one-tenth milliroentgen----[25.8----nanocoulombs----per----kilogram]~~ twenty-five and eight-tenths nanocoulombs per kilogram [0.1 milliroentgen] per hour through at least ~~fifty milliroentgens--[12.9--microcoulombs--per-kilogram]~~ twelve and nine-tenths microcoulombs per kilogram [50 milliroentgens] per hour. Survey instruments acquired before March 1, 1992, and capable of measuring ~~one-tenth milliroentgen-[25.8-nanocoulombs-per-kilogram]~~ twenty-five and eight-tenths nanocoulombs per kilogram [0.1 milliroentgen] per hour through at least ~~twenty milliroentgens-[5.16-microcoulombs-per-kilogram]~~ 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;

(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 ~~microcuries-{becquerels}~~ 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 ~~five-thousandths-microcurie-{185 becquerels}~~ one hundred eighty-five becquerels [0.005 microcurie] of radioactive material on the test sample.

c. Interval of testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source may not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

d. Leaking or contaminated sources. If the test reveals the presence of ~~five-thousandths-microcurie--{185--becquerels}~~ 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 sources.

(2) Sources of radioactive material with a half-life of thirty days or less.

(3) Sealed sources of radioactive material in gaseous form.

(4) Sources of beta and/or gamma-emitting radioactive material with an activity of ~~one-hundred--microcuries [3.7----megabecquerels]~~ three and seven-tenths megabecquerels [100 microcuries] or less.

(5) Sources of alpha-emitting radioactive material with an activity of ~~ten-microcuries--[370--kilobecquerels]~~ three hundred seventy kilobecquerels [10 microcuries] or less.

6. **Quarterly inventory.** Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records or inventories shall be maintained for 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.

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.

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.

   d. 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*
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER*
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

* or CAUTION

10. **Inspection and maintenance.**

a. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of three years for inspection by the department.

b. If any inspection conducted pursuant to subdivision a 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.

c. 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. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the department, the United States nuclear regulatory commission, an agreement state, or a licensing state.

History: Effective June 1, 1986; amended effective June 1, 1992; March 1, 1994; May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-12-09. Notification of incidents, abandonment, and lost sources.

1. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of chapter 33-10-04.1.

2. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

   a. Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations.

   b. Notify the department immediately by telephone and subsequently within thirty days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter must identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

3. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

   a. Advise the well operator of an appropriate method of abandonment, which shall include:

      (1) The immobilization and sealing in place of the radioactive source with a cement plug.

      (2) The setting of a whipstock or other deflection device.

      (3) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by subsection 4.

   b. Notify the department by telephone, facsimile, or overnight express mail giving the circumstances of the loss, and request approval of the proposed abandonment procedures.

   c. File a written report with the department within thirty days of the abandonment. The licensee shall send a copy of the report to:

      North Dakota Industrial Commission
      Oil and Gas Division
      600 East Boulevard
      Bismarck, North Dakota 58505

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) Any other information, such as a warning statement, contained on the permanent identification plaque.

(10) 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.

b. Contain the following information engraved on its face:

(1) The word "CAUTION".

(2) The radiation symbol without the conventional color requirement.

(3) The date of abandonment.

(4) The name of the well operator or well owner.

(5) The well name and well identification numbers or other designation.

(6) The sealed sources by radionuclide and activity.

(7) The source depth and the depth to the top of the plug.

(8) An appropriate warning, depending on the specific circumstances of each abandonment. Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "Do not enlarge casing"; or (c) "Do not reenter the hole", followed by the words, "before contacting the North Dakota state department of health ~~and consolidated laboratories~~".

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.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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.
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.

3. 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 term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as title 49 of the Code of Federal Regulations. 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 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.

4. 8. "Fissile material" means any special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235. Neither natural nor depleted uranium is fissile material 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.

a. Fissile Class I: A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

b. Fissile Class II: A package which may be transported together with other packages in any arrangement but, for criticality control, in numbers which do not exceed an aggregate transport index of fifty. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than one-tenth and not more than ten.

9. "Fissile material package" means a fissile material packaging together with its fissile material contents.

5. 10. "Low specific activity (LSA) material" means any of the following:

a. Uranium or thorium ores and physical or chemical concentrates of those ores.

b. Unirradiated natural or depleted uranium or unirradiated natural thorium.

c. Tritium oxide in aqueous solutions provided the concentration does not exceed five millicuries [185 megabecquerels] per milliliter.

d. Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed:

(1) 0.0001 millicurie [3.7 kilobecquerels] of radionuclides for which the A_2 quantity in appendix A of this chapter is not more than five hundredths curie [1.85 gigabecquerels];

(2) 0.005 millicurie [185 kilobecquerels] of radionuclides for which the A_2 quantity in appendix A of this chapter is more than five hundredths curie [1.85 gigabecquerels] but not more than one curie [37 gigabecquerels]; or

(3) 0.3 millicurie [11.1 megabecquerels] of radionuclides for which the A_2 quantity in appendix A of this chapter is more than one curie [37 gigabecquerels].

e. Objects of nonradioactive material externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible, and the surface contamination, when averaged over an area of one square meter, does not exceed 0.0001 millicurie per square centimeter [3.7 kilobecquerels per centimeter^2] of radionuclides for which the A_2 quantity in appendix A of this chapter is not more than 0.05 curie [1.85 gigabecquerels] or 0.0001 millicurie per square centimeter [37 kilobecquerels per centimeter^2] for other radionuclides.

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 (elg., 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.

6. 12. "Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as special form radioactive material.

7. "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this chapter. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

13. "Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

8. 14. "Rules of the United States department of transportation" means the regulations in 49 CFR parts 100-189.

9. 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.

10. 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 the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package. 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.

11. 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.

~~12.~~ 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.

~~13.~~ 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.

~~14.~~ 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.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

33-10-13-04. Exemptions.

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 licensee is exempt from the requirements of this chapter ~~to the extent that the licensee delivers to a carrier for transport~~ 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 ~~[74 becquerels 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 ~~if the package contains no fissile material~~; ~~or~~

   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 ~~[740 gigabecquerels]~~.;

   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.
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, or who delivers licensed material to a carrier for transport, shall:

   a. Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the United States department of transportation; and

      (1) The licensee shall particularly note United States department of transportation regulations in the following areas:

         (a) Packaging--49 CFR part 173: subparts A and B and I.

         (b) Marking and labeling--49 CFR part 172: subparts D and E.

(c) Placarding--49 CFR part 172: subpart F, especially sections 172.500 through 172.519, 172.556, and appendices B and C.

(d) Accident reporting--49 CFR part 171: sections 171.15 and 171.16.

(e) Shipping papers and emergency information--49 CFR part 172: subparts C and G.

(f) Hazardous material employee training--49 CFR part 172: subpart H.

(g) Hazardous material shipper/carrier registration--49 CFR part 107: subpart G.

(h) Radiation protection program--49 CFR part 172: subpart I.

(2) The licensee shall also note United States department of transportation regulations pertaining to the following modes of transportation:

(a) Rail--49 CFR part 174: subparts A through D and K.

(b) Air--49 CFR part 175.

(c) Vessel--49 CFR part 176: subparts A through F and M.

(d) 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 are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-07. General license - Approved packages.

1. A general license is hereby issued to any licensee of the department to transport, or to deliver to a carrier for

transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the United States nuclear regulatory commission.

2. This general license applies only to a licensee who:

   a. Has a copy of the specific license, certificate of compliance, or other approval of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

   b. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this chapter;

   c. Prior to the licensee's first use of the package, has registered with the United States nuclear regulatory commission; and

   d. Has a quality assurance program ~~required--by--section 33-10-13-20~~ that meets the applicable requirements of 10 CFR 71, subpart H and is approved by the department or the United States nuclear regulatory commission.

3. The general license in subsection 1 applies only when the package approval authorizes use of the package under this general license.

4. For previously approved Type B packages which are not designated as either B(U) or B(M) in the certificate of compliance, this general license is subject to additional restrictions of section 33-10-13-08.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-08. General license - Previously approved Type B packages.

1. A Type B package previously approved by the United States nuclear regulatory commission, but not designated as B(U) or B(M) in the certificate of compliance, may be used under the general license of section 33-10-13-07 with the following additional ~~limitations~~ conditions:

   a. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with United States nuclear regulatory commission regulations; ~~and~~

b. ~~The--package--may-not-be-used-for-a-shipment-to-a-location outside-the-United-States-after--August-31,--1986,--except approved--under--special-arrangement-in-accordance-with-49 CFR-173.471.~~ A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in 49 CFR 173.403; and

c. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

2. A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the United States nuclear regulatory commission but without the designation "-85" in the identification number of the United States nuclear regulatory commission certificate of compliance, may be used under the general license of section 33-10-13-07 with the following additional conditions:

a. Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with subsection 4 of section 33-10-13-14;

b. A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in 49 CFR 173.403; and

c. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-09. General license - Specification container.

1. A general license is issued to any licensee of the department to transport, or to deliver to a carrier for transport, licensed material in a specification container for a Type B quantity of radioactive material as specified in 49 CFR parts 173 and 178.

2. This general license applies only to a licensee who has a quality assurance program ~~required-by-section-33-10-13-20~~ that meets the applicable requirements of 10 CFR 71, subpart H and is approved by the department or the United States nuclear regulatory commission.

3. This general license applies only to a licensee who:

   a. Has a copy of the specification; and

   b. Complies with the terms and conditions of the specification and the applicable requirements of this chapter.

4. The general license in subsection 1 is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States after ~~August 31, 1986, except approved under special arrangements in accordance with 49 CFR 173.472~~, except by multilateral approval, as defined in 49 CFR 173.403.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-10. General license - Use of foreign approved package.

1. A general license is issued to any licensee of the department to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the United States department of transportation as meeting the applicable requirements of 49 CFR 171.12.

2. This general license applies only to international shipments.

3. Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program that meets the applicable requirements of 10 CFR 71, subpart H and is approved by the department or the United States nuclear regulatory commission.

4. This general license applies only to a licensee who:

   a. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

b. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this chapter. With respect to the quality assurance provisions of 10 CFR 71, subpart H, the licensee is exempt from design, construction, and fabrication considerations.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-11. General license - ~~Type A, fissile class II~~ Fissile material, limited quantity per package.

1. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a ~~fissile class II package~~ in accordance with this section.

2. This general license applies only to a licensee who has a quality assurance program that meets the applicable requirements of 10 CFR 71, subpart H and is approved by the department or the United States nuclear regulatory commission.

3. This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

   a. Up to forty grams of uranium-235;

   b. Up to thirty grams of uranium-233;

   c. Up to twenty-five grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

   d. A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in subdivisions a, b, and c of this subsection does not exceed unity.

~~3.~~ 4. a. Except as specified in subdivision b of this subsection this general license applies only when a package containing more than fifteen grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

$$\text{Minimum Transport Index} = \frac{(0.4x + 0.67y + z)\ (1 - 15)}{x+y+z}$$

where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium.

b. For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of fifteen grams.

c. In all cases, the transport index must be rounded up to one decimal place and may not exceed ten.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-12. General license - ~~Restricted,--fissile--class-II~~ Fissile material, limited moderator per package.

1. A general license is ~~hereby~~ issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as-a ~~fissile-class-II-package~~ in accordance with this section.

2. This general license applies only to a licensee who has a quality assurance program that meets the applicable requirements of 10 CFR 71, subpart H and is approved by the department or the United States nuclear regulatory commission.

3. This general license applies only when all of the following requirements are met.

   a. The package contains no more than a Type A quantity of radioactive material.

   b. Neither beryllium nor hydrogenous material enriched in deuterium is present.

   c. The total mass of graphite present does not exceed ~~one hundred-fifty~~ seven and seven-tenths times the total mass of uranium-235 plus plutonium.

   d. Substances having a higher hydrogen density than water are not present, except that polyethylene may be used for packing or wrapping.

   e. Uranium-233 is not present, and the amount of plutonium does not exceed one percent of the amount of uranium-235.

   f. The amount of uranium-235 is limited as follows:

(1) If the fissile radionuclides are not uniformly distributed, the maximum amount of unanium-235 per package may not exceed the value given in the following table:

Table 1

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680*
0.92	1200*

*Pursuant to the department's agreement with the United States nuclear regulatory commission, jurisdiction extends only to three hundred fifty grams of uranium-235.

(2) If the fissile radionuclides are distributed uniformly, the maximum amount of uranium-235 per package may not exceed the value given in the following table:

Table 2

Uranium enrichment in

weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560*
1.35	800*

*Pursuant to the department's agreement with the United States nuclear regulatory commission, jurisdiction extends only to three hundred fifty grams of uranium-235.

---

g. The transport index of each package based on criticality considerations is taken as ten times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with table 1 or 2 above as applicable.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-14. Preliminary determinations. Prior to the first use of any packaging for the shipment of radioactive material:

1. The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;

2. Where the maximum normal operating pressure will exceed ~~thirty-four-and-three-tenths~~ thirty-five kilopascal [5 pounds per square inch] gauge, the licensee shall test the containment system at an internal pressure at least fifty percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

3. The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the United States nuclear regulatory commission; and

4. The licensee shall conspicuously and durably mark the packaging with its model number, gross weight, and a package identification number assigned by the United States nuclear regulatory commission.

History: Effective June 1, 1992; amended effective May 1, 1998.
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. a. The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. ~~The level of removable radioactive contamination may be determined by wiping an area of three hundred square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in subdivision b of this subsection, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in table 3 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are~~

used;--the-detection-efficiency-of-the-method-used-must-be taken-into-account--and--in--no--case--may--the--removable contamination--on--the--external--surfaces--of-the-package exceed-ten-times-the-limits-listed-in-table-3., and within the limits specified in 49 CFR 173.443;

Table-3
Removable-External-Radioactive-Contamination-Wipe-Limits

Contaminant	Maximum-Permissible Limits	
*-uCi/cm^2	dpm/cm^2	
Beta-gamma-emitting-radionuclides; all-radionuclides-with-half-lives-less-than ten-days;-natural-uranium;-natural-thorium; uranium-235;-uranium-238;-thorium-232; thorium-228-and-thorium-230-when-contained-in ores-or-physical-concentrates	10^{-5}	22
All-other-alpha-emitting-radionuclides	10^{-6}	2.2

*To--convert--microcuries--(uCi)--to--SI--units-of-megabecquerels; multiply-the-values-by-0.037.

b.--In--the--case--of--packages--transported--as-exclusive-use shipments--by--rail--or--highway---only,---the---removable radioactive--contamination--at--any--time-during-transport must--not--exceed--ten--times--the--levels--prescribed--in subdivision-a.---The--levels-at-the-beginning-of-transport must-not-exceed-the-levels-in-subdivision-a;

9. External radiation levels around the package and around the vehicle, if applicable, will not exceed two hundred--millirems millisieverts per hour [2-millisieverts 200 millirems per hour] at any point on the external surface of the package at any time during transportation. The transport index may 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. Two hundred----millirems millisieverts per hour [2-millisieverts 200 millirems per hour] on the accessible external surface of the package unless the following conditions are met, in which case the limit is one thousand----millirems ten millisieverts per hour [10-millisieverts 1000 millirems per hour];

(1) The shipment is made in a closed transport vehicle;

(2) Provisions are made to secure the package 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 ~~hundred---millirems~~ millisieverts per hour [~~2-millisieverts~~ 200 millirems per hour] at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flatbed style vehicle, with a personnel barrier ~~(A-flatbed-style-vehicle with-a--personnel--barrier--shall--have--radiation--levels determined--at--vertical-planes.--If-no-personnel-barrier, the--package--cannot---exceed---200-millirems---per---hour [2-millisieverts--per-hour]-at-the-surface.),~~ 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. ~~Ten---millirems~~ One-tenth millisievert per hour [~~0.1-millisieverts~~ 10 millirems per hour] at any point two meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flatbed style vehicle, at any point two meters from the vertical planes projected from the outer edges of the vehicle; and

d. Two ~~millirems~~ hundredths millisieverts per hour [~~0.02-millisieverts~~ 2 millirems per hour] in any normally occupied positions of the vehicle, 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; ~~and~~

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 ~~one--hundred~~ thirty-eight degrees Celsius [100 degrees Fahrenheit ~~[38-degrees---Celsius]~~ and in the shade, no accessible surface of a package would have a temperature exceeding ~~one--hundred--twenty-two~~ fifty degrees Celsius [122 degrees Fahrenheit ~~[50-degrees-Celsius]~~ in a nonexclusive use shipment or ~~one-hundred-eighty-degrees-Fahrenheit-[82-degrees Celsius]~~ 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.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-16. Air transport of plutonium.

1. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this chapter or included indirectly by citation of the United States department of transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

~~1.~~ a. The plutonium is contained in a medical device designed for individual human application;

~~2.~~ b. The plutonium is contained in a material in which the specific activity is not greater than ~~two--thousandths~~ seventy becquerels per gram [0.002 microcuries per gram ~~[74-becquerel-per-gram]~~ of material and in which the radioactivity is essentially uniformly distributed;

~~3.~~ c. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with section 33-10-13-05; or

~~4.~~ d. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the certificate of compliance for that package issued by the United States nuclear regulatory commission.

2. Nothing in subsection 1 is to be interpreted as removing or diminishing the requirements of section 33-10-13-11.

3. For a shipment of plutonium by air which is subject to subdivision d of subsection 1, the licensee shall, through special arrangement with the carrier, require compliance with

49 CFR 175.704, as applicable to the air transport of plutonium.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-04, 28-32-02

33-10-13-18. Reports. The licensee shall report to the department within thirty days:

1. Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and

2. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.

3. Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-19. Advance notification of transport 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 ~~(A list of the mailing addresses of the governors and governors' designees is available upon request from the director, state programs, office of governmental and public affairs, United States nuclear regulatory commission, Washington, D.C. 20555.)~~, 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)--Five--thousand-curies-[185-terabecquerels]-of-special form-radionuclides;~~

~~(2)--Five----thousand---curies---[185-terabecquerels]---of uncompressed---gases---of---argon-41,----krypton-85m, krypton-87,-xenon-131m,-or-xenon-135;~~

~~(3)--Fifty---thousand---curies---[1.85-petabecquerels]--of argon-37,-or-of-uncompressed-gases-of--krypton-85--or xenon-133,--or--of--hydrogen-3--as-a-gas,-as-luminous paint,-or-absorbed-on-solid-material;~~

~~(4)--Twenty----curies----[740-gigabecquerels]---of---other nonspecial-form-radionuclides-for-which--A_2 is--less than-or-equal-to-four-curies-[148-gigabecquerels];-or~~

~~(5)--Two--hundred--curies--[7.4-terabecquerels]--of--other nonspecial-form-radionuclides-for-which-A_2 is-greater than-four-curies-[148-gigabecquerels].~~

~~3.--Each---advance--notification--required--by--subsection-1--must contain-the-following-information:~~

~~a.--The--name,--address,--and-telephone-number-of-the-shipper, carrier,-and-receiver-of-the-shipment;~~

~~b.--A--description--of--the--nuclear--waste--contained--in-the shipment-as-required-by-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.~~

~~4.--The--notification--required--by--subsection-1--must-be-made-in writing--to--the--office--of--each--appropriate--governor,--or~~

~~governor's--designee,--and--to-the-department.--A-notification delivered-by-mail-must--be--postmarked--at--least--seven--days before--the--beginning--of--the--seven-day-period-during-which departure--of--the--shipment--is--estimated---to---occur.----A notification--delivered--by-messenger-must-reach-the-office-of the-governor,-or--governor's--designee,--at--least--four--days before--the--beginning--of--the--seven-day-period-during-which departure-of-the-shipment-is-estimated-to-occur.---A--copy--of the--notification--must--be--retained--by-the-licensee-for-one year.~~

~~5.--The--licensee--shall--notify--each--appropriate--governor,--or governor's-designee,-and-the--department--of--any--changes--to schedule--information-provided-pursuant-to-subsection-1.--Such notification-must-be-by-telephone-to-a-responsible--individual in--the-office-of-the-governor,-or-governor's-designee,-of-the appropriate-state-or-states.--The-licensee-shall-maintain--for one-year-a-record-of-the-name-of-the-individual-contacted.~~

~~6.--Each--licensee-who-cancels-a-nuclear-waste-shipment,-for-which advance-notification-has-been-sent,-shall-send-a--cancellation notice--to--the--governor,--or--governor's--designee,--of-each appropriate-state-and-to-the-department.--A-copy-of-the-notice must-be-retained-by-the-licensee-for-one-year.~~

(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.

History: Effective June 1, 1992; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 28-32-02

33-10-13-20. Quality assurance requirements.

~~1. Each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.~~

~~2. The licensee shall identify the material and components to be covered by the quality assurance program.~~

~~3. Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.~~

~~4. Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the department of its quality assurance program.~~

~~5. The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material must be maintained for a period of two years after shipment.~~ Repealed effective May 1, 1998.

~~**History:** Effective June 1, 1992.~~
~~**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. Single radionuclides.

a. For a single radionuclide of known identity, the values of A_1 and A_2 are taken from table I if listed there. The values A_1 and A_2 in table I are also applicable for the radionuclide contained in (α,n) or (γ,n) neutron sources.

b. For any single radionuclide whose identity is known but which is not listed in table I, the value of A_1 and A_2 are determined according to the following procedure.

(1) If the radionuclide emits only one type of radiation, A_1 is determined according to the following method. For radionuclides emitting different kinds of radiation, A_1 is the most restrictive value of those determined for each kind of radiation. However, in either case, A_1 is restricted to a maximum of one thousand curies [37 terabecquerels]. If a parent nuclide decays into a shorter lived daughter with a half-life not greater than ten days, A_1 is calculated for both the parent and the daughter, and the more limiting of the two values is assigned to the parent nuclide.

(a) For gamma emitters, A_1 is determined by the expression.

$$A_1 = \frac{9 \text{ curies}}{\Gamma}$$

where Γ is the gamma-ray constant, corresponding to the dose in roentgens per curie-hour at 1 meter, and the number 9 results from the choice of 1 rem per hour at a distance of 3 meters as the reference dose-equivalent rate.

(b) For x ray emitters, A_1 is determined by the atomic number of the nuclide.

for $Z \leq 55$, $A_1 = 1000$ Ci [37 terabecquerels], and

for $Z > 55$, $A_1 = 200$ Ci [7.4 terabecquerels]

where Z is the atomic number of the nuclide.

(c) For beta emitters, A_1 is determined by the maximum beta energy (E_{max}) according to Table II; and

(d) For alpha emitters, A_1 is determined by the expression:

$$A_1 = 1000\ A_3$$

where A_3 is the value listed in table III;

(2) A_2 is the more restrictive of the following two values:

(a) The corresponding A_1; and

(b) The value A_3 obtained from table III.

c. For any single radionuclide whose identity is unknown, the value of A_1 is taken to be two curies [74 gigabecquerels] and the value of A_2 is taken to be two-thousandths curie [74 megabecquerels]. However, if the atomic number of the radionuclide is known to be less than eighty-two, the value of A_1 is taken to be ten curies [370 gigabecquerels] and the value of A_2 is taken to be four-tenths curie [14.8 gigabecquerels].

2. Mixtures of Radionuclides, Including Radioactive Decay Chains.

a. For mixed fission products, the activity limit may be assumed if a detailed analysis of the mixture is not carried out,

A_1 = 10 Ci [370 gigabecquerels]

A_2 = 0.4 Ci [14.8 gigabecquerels]

b. A single radioactive decay chain is considered to be a single radionuclide when the radionuclides are present in their naturally occurring proportions and no daughter nuclide has a half-life either longer than ten days or longer than that of the parent nuclide. The activity to be taken into account and the A_1 or A_2 value from table I to be applied are those corresponding to the parent nuclide of that chain. When calculating A_1 or A_2 values, radiation emitted by daughters must be considered. However, 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 daughter nuclides are considered to be mixtures of different nuclides.

~~c. In the case of a mixture of different radionuclides, where the identity and activity of each radionuclide are known, the permissible activity of each radionuclide R_1, R_2 . . . R_n is such that $F_1 + F_2 + \ldots F_n$ is not greater than unity, where:~~

~~$F_1 = \frac{\text{Total activity of } R_1}{A_1(R_1)}$~~

~~$F_2 = \frac{\text{Total activity of } R_2}{A_1(R_2)}$~~

~~$F_n = \frac{\text{Total activity of } R_n}{A_1(R_n)}$ and~~

~~A_1 (R_1, R_2 . . . R_n) is the value of A_1 or A_2 as appropriate for the nuclide R_1, R_2 . . . R_n.~~

~~d. When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the formula given in paragraph 2.c is applied to establish the values of A_1 or A_2 as appropriate. All the radionuclides whose individual activities are not known (their total activity will, however, be known) are classed in a single group and the most restrictive value of A_1 and A_2 applicable to any one of them is used as the value of A_1 or A_2 in the denominator of the fraction.~~

~~e. Where the identity of each radionuclide is known but the individual activity of none of the radionuclides is known, the most restrictive value of A_1 or A_2 applicable to any one of the radionuclides present is adopted as the applicable value.~~

~~f. When the identity of none of the nuclides is known, the value of A_1 is taken to be two curies [74 gigabecquerels] and the value of A_2 is taken to be two thousandths [74 megabecquerels]. However, if alpha emitters are known to be absent, the value of A_2 is taken to be four-tenths curie [14.8 gigabecquerels].~~

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 10 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 10 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 radionuclide 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.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 28-32-02

~~**Table I**~~

~~**A_1 and A_2 Values for Radionuclides**~~

~~**(See Footnotes at end of Table)**~~

~~Symbol of radionuclide~~	~~Element and atomic number~~	~~A_1(Ci)~~	~~A_2(Ci)~~	~~Specific Activity (Ci/g)~~
~~Ac-227~~	~~Actinium (89)~~	~~1000~~	~~0.003~~	~~7.2×10^{1}~~
~~Ac-228~~		~~10~~	~~4~~	~~2.2×10^{6}~~
~~Ag-105~~	~~Silver (47)~~	~~40~~	~~40~~	~~3.1×10^{4}~~
~~Ag-110m~~		~~7~~	~~7~~	~~4.7×10^{3}~~
~~Ag-111~~		~~100~~	~~20~~	~~1.6×10^{5}~~
~~Am-241~~	~~Americium (95)~~	~~8~~	~~0.008~~	~~3.2~~
~~Am-243~~		~~8~~	~~0.008~~	~~1.9×10^{-1}~~
~~Ar-37 (compressed or uncompressed)*~~	~~Argon (18)~~	~~1000~~	~~1000~~	~~1.0×10^{5}~~
~~Ar-41 (uncompressed)*~~		~~20~~	~~20~~	~~4.3×10^{7}~~
~~Ar-41 (compressed)*~~		~~1~~	~~1~~	~~4.3×10^{7}~~
~~As-73~~	~~Arsenic (33)~~	~~1000~~	~~400~~	~~2.4×10^{4}~~
~~As-74~~		~~20~~	~~20~~	~~1.0×10^{5}~~
~~As-76~~		~~10~~	~~10~~	~~1.6×10^{6}~~
~~As-77~~		~~300~~	~~20~~	~~1.1×10^{6}~~
~~At-211~~	~~Astatine (85)~~	~~200~~	~~7~~	~~2.1×10^{6}~~
~~Au-193~~	~~Gold (79)~~	~~200~~	~~200~~	~~9.3×10^{5}~~
~~Au-196~~		~~30~~	~~30~~	~~1.2×10^{5}~~
~~Au-198~~		~~40~~	~~20~~	~~2.5×10^{5}~~
~~Au-199~~		~~200~~	~~25~~	~~2.1×10^{5}~~
~~Ba-131~~	~~Barium (56)~~	~~40~~	~~40~~	~~8.7×10^{4}~~
~~Ba-133~~		~~40~~	~~40~~	~~4.0×10^{2}~~

Table I (Continued-2)

Symbol of radionuclide	Element and atomic number	A_1 (Ci)	A_2 (Ci)	Specific Activity (Ci/g)
Ba-140		20	20	7.3×10^4
Be-7	Beryllium (4)	300	300	3.5×10^5
Bi-206	Bismuth (83)	5	5	9.9×10^4
Bi-207		10	10	2.2×10^3
Bi-210 (RaE)		100	4	1.2×10^5
Bi-212		6	6	1.5×10^7
Bk-249	Berkelium (97)	1000	1	1.8×10^3
Br-77	Bromine (35)	70	25	7.1×10^5
Br-82		6	6	1.1×10^6
C-11	Carbon (6)	20	20	8.4×10^8
C-14		1000	60	4.6
Ca-45	Calcium (20)	1000	25	1.9×10^4
Ca-47		20	20	5.9×10^5
Cd-109	Cadmium (48)	1000	70	2.6×10^3
Cd-115m		30	30	2.6×10^4
Cd-115		80	20	5.1×10^5
Ce-139	Cerium (58)	100	100	6.5×10^3
Ce-141		300	25	2.8×10^4
Ce-143		60	20	6.6×10^5
Ce-144		10	7	3.2×10^3
Cf-249	Californium (98)	2	0.002	3.1
Cf-250		7	0.007	1.3×10^3
Cf-252		2	0.009	6.5×10^3
Cl-36	Chlorine (17)	300	10	3.2×10^{-2}
Cl-38		10	10	1.3×10^9
Cm-242	Curium (96)	200	0.2	3.3×10^3
Cm-243		9	0.009	4.2×10^1

Table I (Continued-3)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Cm-244		10	0.01	8.2×10^{1}
Cm-245		6	0.006	1.0×10^{-1}
Cm-246		6	0.006	3.6×10^{-1}
Co-56	Cobalt (27)	5	5	3.0×10^{4}
Co-57		90	90	8.5×10^{3}
Co-58m		1000	1000	5.9×10^{6}
Co-58		20	20	3.1×10^{4}
Co-60		7	7	1.1×10^{3}
Cr-51	Chromium (24)	600	600	9.2×10^{4}
Cs-129	Cesium (55)	40	40	7.6×10^{5}
Cs-131		1000	1000	1.0×10^{5}
Cs-134m		1000	10	7.4×10^{6}
Cs-134		10	10	1.2×10^{3}
Cs-135		1000	25	8.8×10^{-4}
Cs-136		7	7	7.4×10^{4}
Cs-137		30	10	9.8×10^{1}
Cu-64	Copper (29)	80	25	3.8×10^{6}
Cu-67		200	25	7.9×10^{5}
Dy-165	Dysprosium (66)	100	20	8.2×10^{6}
Dy-166		1000	200	2.3×10^{5}
Er-169	Erbium (68)	1000	25	8.2×10^{4}
Er-171		50	20	2.4×10^{6}
Eu-152m	Europium (63)	30	30	2.2×10^{6}
Eu-152		20	10	1.9×10^{2}
Eu-154		10	5	1.5×10^{2}

Table I (Continued-4)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Eu 155		400	60	1.4×10^3
F 18	Fluorine (9)	20	20	9.3×10^7
Fe 52	Iron (26)	5	5	7.3×10^6
Fe 55		1000	1000	2.2×10^3
Fe 59		10	10	4.9×10^4
Ga 67	Gallium (31)	100	100	6.0×10^5
Ga 68		20	20	4.0×10^7
Ga 72		7	7	3.1×10^6
Gd 153	Gadolinium (64)	200	100	3.6×10^3
Gd 159		300	20	1.1×10^6
Ge 68	Germanium (32)	20	10	7.0×10^3
Ge 71		1000	1000	1.6×10^5
H-3	Hydrogen (1) see T-Tritium			
Hf 181	Hafnium (72)	30	25	1.6×10^4
Hg 197m	Mercury (80)	200	200	6.6×10^5
Hg 197		200	200	2.5×10^5
Hg 203		80	25	1.4×10^4
Ho 166	Holmium (67)	30	30	6.9×10^5
I 123	Iodine (53)	50	50	1.9×10^6
I 125		1000	70	1.7×10^4
I 126		40	10	7.8×10^4
I 129		1000	2	1.6×10^{-4}
I 131		40	10	1.2×10^5
I 132		7	7	1.1×10^7
I 133		30	10	1.1×10^6

Table I (Continued-5)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
I-134		8	8	2.7×10^{7}
I-135		10	10	3.5×10^{6}
In-111	Indium (49)	30	25	4.2×10^{5}
In-113m		60	60	1.6×10^{7}
In-114m		30	20	2.3×10^{4}
In-115m		100	20	6.1×10^{6}
Ir-190	Iridium (77)	10	10	6.2×10^{4}
Ir-192		20	10	9.1×10^{3}
Ir-194		10	10	8.5×10^{5}
K-42	Potassium (19)	10	10	6.0×10^{6}
K-43		20	10	3.3×10^{6}
Kr-85m (uncompressed)*	Krypton (36)	100	100	8.4×10^{6}
Kr-85m (compressed)*		3	3	8.4×10^{6}
Kr-85 (uncompressed)*		1000	1000	4.0×10^{2}
Kr-85 (compressed)*		5	5	4.0×10^{2}
Kr-87 (uncompressed)*		20	20	2.8×10^{7}
Kr-87 (compressed)*		0.6	0.6	2.8×10^{7}
La-140	Lanthanum (57)	30	30	5.6×10^{5}
Lu-177	Lutetium (71)	300	25	1.1×10^{5}
MFP	Mixed Fission products	10	0.4	---
Mg-28	Magnesium (12)	6	6	5.2×10^{6}
Mn-52	Manganese (25)	5	5	4.4×10^{5}
Mn-54		20	20	8.3×10^{3}
Mn-56		5	5	2.2×10^{7}
Mo-99	Molybdenum (42)	100	20	4.7×10^{5}

Table I (Continued-6)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
N-13	Nitrogen (7)	20	10	1.5×10^3
Na-22	Sodium (11)	8	8	6.3×10^3
Na-24		5	5	8.7×10^4
Nb-93m	Niobium (41)	1000	200	1.1×10^1
Nb-95		20	20	3.9×10^2
Nb-97		20	20	2.6×10^5
Nd-147	Neodymium (60)	100	20	8.0×10^2
Nd-149		30	20	1.1×10^5
Ni-59	Nickel (28)	1000	900	8.1×10^{-2}
Ni-63		1000	100	4.6×10^0
Ni-65		10	10	1.9×10^5
Np-237	Neptunium (93)	5	0.005	6.9×10^{-4}
Np-239		200	25	2.3×10^3
Os-185	Osmium (76)	20	20	7.3×10^1
Os-191		600	200	4.6×10^2
Os-191m		200	200	1.2×10^4
Os-193		100	20	5.3×10^3
P-32	Phosphorus (15)	30	30	2.9×10^3
Pa-230	Protactinium (91)	20	0.8	3.2×10^2
Pa-231		2	0.002	4.5×10^{-2}
Pa-233		100	100	2.1×10^2
Pb-201	Lead (82)	20	20	1.7×10^4
Pb-210		100	0.2	8.8×10^0
Pb-212		6	5	1.4×10^4
Pd-103	Palladium (46)	1000	700	7.5×10^2

Table I (Continued-7)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Pd-109		100	20	2.1×10^{6}
Pm-147	Promethium (61)	1000	25	9.4×10^{2}
Pm-149		100	20	4.2×10^{5}
Po-210	Polonium (84)	200	0.2	4.5×10^{3}
Pr-142	Praseodymium (59)	10	10	1.2×10^{4}
Pr-143		300	20	6.6×10^{4}
Pt-191	Platinum (78)	100	100	2.3×10^{5}
Pt-193m		200	200	2.0×10^{5}
Pt-197m		300	20	1.2×10^{7}
Pt-197		300	20	8.8×10^{5}
Pu-238	Plutonium (94)	3	0.003	1.7×10^{1}
Pu-239		2	0.002	6.2×10^{-2}
Pu-240		2	0.002	2.3×10^{-1}
Pu-241		1000	0.1	1.1×10^{2}
Pu-242		3	0.003	3.9×10^{-3}
Ra-223	Radium (88)	50	0.2	5.0×10^{4}
Ra-224		6	0.5	1.6×10^{5}
Ra-226		10	0.05	1.0
Ra-228		10	0.05	2.3×10^{2}
Rb-81	Rubidium (37)	30	24	8.2×10^{6}
Rb-86		30	30	8.1×10^{4}
Rb-87		Unlimited	Unlimited	6.6×10^{-8}
Rb (natural)		Unlimited	Unlimited	1.8×10^{-8}
Re-186	Rhenium(75)	100	20	1.9×10^{5}
Re-187		Unlimited	Unlimited	3.8×10^{-8}
Re-188		10	10	1.0×10^{6}

Table I (Continued-8)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Re (natural)		Unlimited	Unlimited	2.4×10^{-9}
Rh 103m	Rhodium (45)	1000	1000	3.2×10^{7}
Rh 105		200	25	8.2×10^{5}
Rn 222	Radon (86)	10	2	1.5×10^{5}
Ru 97	Ruthenium (44)	80	80	5.5×10^{5}
Ru 103		30	25	3.2×10^{4}
Ru 105		20	20	6.6×10^{6}
Ru 106		10	7	3.4×10^{3}
S 35	Sulphur (16)	1000	60	4.3×10^{4}
Sb 122	Antimony (51)	30	30	3.9×10^{5}
Sb 124		5	5	1.8×10^{4}
Sb 125		40	25	1.4×10^{3}
Sc 46	Scandium (21)	8	8	3.4×10^{4}
Sc 47		200	20	8.2×10^{5}
Sc 48		5	5	1.5×10^{6}
Se 75	Selenium (34)	40	40	1.4×10^{4}
Si 31	Silicon (14)	100	20	3.9×10^{7}
Sm 147	Samarium (62)	Unlimited	Unlimited	2.0×10^{-9}
Sm 151		1000	90	2.6×10^{1}
Sm 153		300	20	4.4×10^{5}
Sn 113	Tin (50)	60	60	1.0×10^{4}
Sn 119m		100	100	4.4×10^{3}
Sn 125		10	10	1.1×10^{5}
Sr 85m	Strontium (38)	80	80	3.2×10^{7}
Sr 85		30	30	2.4×10^{4}
Sr 85m		50	50	1.2×10^{7}

Table I (Continued-9)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Sr 89		100	10	2.9×10^{4}
Sr 90		10	0.4	1.5×10^{3}
Sr 91		10	10	3.6×10^{6}
Sr 92		10	10	1.3×10^{7}
T (uncompressed)*	Tritium (1)	1000	1000	9.7×10^{3}
T (compressed)*		1000	1000	9.7×10^{3}
T (activated luminous paint)		1000	1000	9.7×10^{3}
T (adsorbed on solid carrier)		1000	1000	9.7×10^{3}
T (tritiated water)		1000	1000	9.7×10^{3}
T (other forms)		20	20	9.7×10^{3}
Ta 182	Tantalum (73)	20	20	6.2×10^{3}
Tb 160	Terbium (65)	20	10	1.1×10^{4}
Tc 96m	Technetium (43)	1000	1000	3.8×10^{7}
Tc 96		6	6	3.2×10^{5}
Tc 97m		1000	200	1.5×10^{4}
Tc 97		1000	400	1.4×10^{-3}
Tc 99m		100	100	5.2×10^{6}
Tc 99		1000	25	1.7×10^{-2}
Te 125m	Tellurium (52)	1000	100	1.8×10^{4}
Te 127m		300	20	4.0×10^{4}
Te 127		300	20	2.6×10^{6}
Te 129m		30	10	2.5×10^{4}
Te 129		100	20	2.0×10^{7}
Te 131m		10	10	8.0×10^{5}

Table I (Continued-10)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Te 132		7	7	3.1×10^5
Th 227	Thorium (90)	200	0.2	3.2×10^4
Th 228		6	0.008	8.3×10^2
Th 230		3	0.003	1.9×10^{-2}
Th 231		1000	25	5.3×10^5
Th 232		Unlimited	Unlimited	1.1×10^{-7}
Th 234		10	10	2.3×10^4
Th (natural)		Unlimited	Unlimited	2.2×10^{-7}
Th (irradiated)**		---	---	---
Tl 200	Thallium (81)	20	20	5.8×10^5
Tl 201		200	200	2.2×10^5
Tl 202		40	40	5.4×10^4
Tl 204		300	10	4.3×10^2
Tm 170	Thulium (69)	300	10	6.0×10^3
Tm 171		1000	100	1.1×10^3
U 230	Uranium (92)	100	0.1	2.7×10^4
U 232		30	0.03	2.1×10^2
U 233		100	0.1	9.5×10^{-3}
U 234		100	0.1	6.2×10^{-3}
U 235		100	0.2	2.1×10^{-6}
U 236		200	0.2	6.3×10^{-5}
U 238		Unlimited	Unlimited	3.3×10^{-7}
U (natural)		Unlimited	Unlimited	(see Table IV)
U (enriched) <	20%	Unlimited	Unlimited	(see Table IV)
	20% or greater	100	0.1	(see Table IV)

Table I (Continued-11)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
U (depleted)	(see Table IV)	Unlimited		Unlimite
U (irradiated)***		---	---	---
V 48	Vanadium (23)	6	6	1.7×10^5
W 181	Tungsten (74)	200	100	5.0×10^3
W 185		1000	25	9.7×10^{-3}
W 187		40	20	7.0×10^5
Xe 127 (uncompressed)*	Xenon (54)	70	70	2.8×10^4
Xe 127 (compressed)*		5	5	2.8×10^4
Xe 131m (compressed)*		10	10	1.0×10^5
Xe 131m (uncompressed)*		100	100	1.0×10^5
Xe 133 (uncompressed)*		1000	1000	1.9×10^5
Xe 133 (compressed)*		5	5	1.9×10^5
Xe 135 (uncompressed)*		70	70	2.5×10^5
Xe 135 (compressed)*		2	2	2.5×10^5
Y 87	Yttrium (39)	20	20	4.5×10^3
Y 90		10	10	2.5×10^5
Y 91m		30	30	4.1×10^7
Y 91		30	30	2.5×10^4
Y 92		10	10	9.5×10^6
Y 93		10	10	3.2×10^6
Yb 169	Ytterbium (70)	80	80	2.3×10^5
Yb 175		400	25	1.8×10^5
Zn 65	Zinc (30)	30	30	8.0×10^3
Zn 69m		40	20	3.3×10^6
Zn 69		300	20	5.3×10^7

Table I (Continued-12)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Zr 93	Zirconium (40)	1000	200	3.5×10^{-3}
Zr 95		20	20	2.1×10^{4}
Zr 97		20	20	2.0×10^{6}

* For the purpose of table I, compressed gas means a gas at a pressure which exceeds the ambient atmospheric pressure at the location where the containment system was closed.

** The values of A_1 and A_2 must be calculated in accordance with the procedure specified in appendix A, paragraph c, taking into account the activity of the fission products and of the uranium-233 in addition to that of the thorium.

*** The values of A_1 and A_2 must be calculated in accordance with the procedure specified in appendix A, paragraph c, taking into account the activity of the fission products and plutonium isotopes in addition to that of the uranium.

STAFF COMMENT. The following Table I is all new material and is not underscored so as to improve readability.

TABLE I
A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ac-225	Actinium(89)	0.6	16.2	1E-2	0.270	2.1E3	5.8E4
Ac-227		40	1080	2E-5	5.41E-4	2.7	7.2E1
Ac-228		0.6	16.2	0.4	10.8	8.4E4	2.2E6
Ag-105	Silver(47)	2	54.1	2	54.1	1.1E3	3.0E4
Ag-108m		0.6	16.2	0.6	16.2	9.7E-1	2.6E1
Ag-110m		0.4	10.8	0.4	10.8	1.8E2	4.7E3
Ag-111		0.6	16.2	0.5	13.5	5.8E3	1.6E5
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	7.0E-4	1.9E-2
Am-241	Americium(95)	2	54.1	2E-4	5.41E-3	1.3E-1	3.4
Am-242m		2	54.1	2E-4	5.41E-3	3.6E-1	1.0E1
Am-243		2	54.1	2E-4	5.41E-3	7.4E-3	2.0E-1
Ar-37	Argon(18)	40	1080	40	1080	3.7E3	9.9E4
Ar-39		20	541	20	541	1.3	3.4E1
Ar-41		0.6	16.2	0.6	16.2	1.5E6	4.2E7
Ar-42		0.2	5.41	0.2	5.41	9.6	2.6E2
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	6.2E4	1.7E6
As-73		40	1080	40	1080	8.2E2	2.2E4
As-74		1	27.0	0.5	13.5	3.7E3	9.9E4
As-76		0.2	5.41	0.2	5.41	5.8E4	1.6E6
As-77		20	541	0.5	13.5	3.9E4	1.0E6
At-211	Astatine(85)	30	811	2	54.1	7.6E4	2.1E6
Au-193	Gold(79)	6	162	6	162	3.4E4	9.2E5
Au-194		1	27.0	1	27.0	1.5E4	4.1E5
Au-195		10	270	10	270	1.4E2	3.7E3
Au-196		2	54.1	2	54.1	4.0E3	1.1E5
Au-198		3	81.1	0.5	13.5	9.0E3	2.4E5
Au-199		10	270	0.9	24.3	7.7E3	2.1E5
Ba-131	Barium(56)	2	54.1	2	54.1	3.1E3	8.4E4

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ba-133m		10	270	0.9	24.3	2.2E4	6.1E5
Ba-133		3	81.1	3	81.1	9.4	2.6E2
Ba-140		0.4	10.8	0.4	10.8	2.7E3	7.3E4
Be-7	Beryllium(4)	20	541	20	541	1.3E4	3.5E5
Be-10		20	541	0.5	13.5	8.3E-4	2.2E-2
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	1.5E-3	4.2E4
Bi-206		0.3	8.11	0.3	8.11	3.8E3	1.0E5
Bi-207		0.7	18.9	0.7	18.9	1.9	5.2E1
Bi-210m		0.3	8.11	3E-2	0.811	2.1E-5	5.7E-4
Bi-210		0.6	16.2	0.5	13.5	4.6E3	1.2E5
Bi-212		0.3	8.11	0.3	8.11	5.4E5	1.5E7
Bk-247	Berkelium(97)	2	54.1	2E-4	5.41E-3	3.8E-2	1.0
Bk-249		40	1080	8E-2	2.16	6.1E1	1.6E3
Br-76	(Bromine)(35)	0.3	8.11	0.3	8.11	9.4E4	2.5E6
Br-77		3	81.1	3	81.1	2.6E4	7.1E5
Br-82		0.4	10.8	0.4	10.8	4.0E4	1.1E6
C-11	Carbon(6)	1	27.0	0.5	13.5	3.1E7	8.4E8
C-14		40	1080	2	54.1	1.6E-1	4.5
Ca-41	Calcium(20)	40	1080	40	1080	3.1E-3	8.5E-2
Ca-45		40	1080	0.9	24.3	6.6E2	1.8E4
Ca-47		0.9	24.3	0.5	13.5	2.3E4	6.1E5
Cd-109	Cadmium(48)	40	1080	1	27.0	9.6E1	2.6E3
Cd-113m		20	541	9E-2	2.43	8.3	2.2E2
Cd-115m		0.3	8.11	0.3	8.11	9.4E2	2.5E4
Cd-115		4	108	0.5	13.5	1.9E4	5.1E5
Ce-139	Cerium(58)	6	162	6	162	2.5E2	6.8E3
Ce-141		10	270	0.5	13.5	1.1E3	2.8E4
Ce-143		0.6	16.2	0.5	13.5	2.5E4	6.6E5
Ce-144		0.2	5.41	0.2	5.41	1.2E2	3.2E3
Cf-248	Californium(98)	30	811	3E-3	8.11E-2	5.8E1	1.6E3
Cf-249		2	54.1	2E-4	5.41E-3	1.5E-1	4.1

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Cf-250		5	135	5E-4	1.35E-2	4.0	1.1E2
Cf-251		2	54.1	2E-4	5.41E-3	5.9E-2	1.6
Cf-252		0.1	2.70	1E-3	2.70E-2	2.0E1	5.4E2
Cf-253		40	1080	6E-2	1.62	1.1E3	2.9E4
Cf-254		3E-3	8.11E-2	6E-4	1.62E-2	3.1E2	8.5E3
Cl-36	Chlorine(17)	20	541	0.5	13.5	1.2E-3	3.3E-2
Cl-38		0.2	5.41	0.2	5.41	4.9E6	1.3E8
Cm-240	Curium(96)	40	1080	2E-2	0.541	7.5E2	2.0E4
Cm-241		2	54.1	0.9	24.3	6.1E2	1.7E4
Cm-242		40	1080	1E-2	0.270	1.2E2	3.3E3
Cm-243		3	81.1	3E-4	8.11E-3	1.9	5.2E1
Cm-244		4	108	4E-4	1.08E-2	3.0	8.1E1
Cm-245		2	54.1	2E-4	5.41E-3	6.4E-3	1.7E-1
Cm-246		2	54.1	2E-4	5.41E-3	1.1E-2	3.1E-1
Cm-247		2	54.1	2E-4	5.41E-3	3.4E-6	9.3E-5
Cm-248		4E-2	1.08	5E-5	1.35E-3	1.6E-4	4.2E-3
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	1.1E5	3.1E6
Co-56		0.3	8.11	0.3	8.11	1.1E3	3.0E4
Co-57		8	216	8	216	3.1E2	8.4E3
Co-58m		40	1080	40	1080	2.2E5	5.9E6
Co-58		1	27.0	1	27.0	1.2E3	3.2E4
Co-60		0.4	10.8	0.4	10.8	4.2E1	1.1E3
Cr-51	Chromium(24)	30	811	30	811	3.4E3	9.2E4
Cs-129	Cesium(55)	4	108	4	108	2.8E4	7.6E5
Cs-131		40	1080	40	1080	3.8E3	1.0E5
Cs-132		1	27.0	1	27.0	5.7E3	1.5E5
Cs-134m		40	1080	9	243	3.0E5	8.0E6
Cs-134		0.6	16.2	0.5	13.5	4.8E1	1.3E3
Cs-135		40	1080	0.9	24.3	4.3E-5	1.2E-3
Cs-136		0.5	13.5	0.5	13.5	2.7E3	7.3E4
Cs-137		2	54.1	0.5	13.5	3.2	8.7E1

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Cu-64	Copper(29)	5	135	0.9	24.3	1.4E5	3.9E6
Cu-67		9	243	0.9	24.3	2.8E4	7.6E5
Dy-159	Dysprosium(66)	20	541	20	541	2.1E2	5.7E3
Dy-165		0.6	16.2	0.5	13.5	3.0E5	8.2E6
Dy-166		0.3	8.11	0.3	8.11	8.6E3	2.3E5
Er-169	Erbium(68)	40	1080	0.9	24.3	3.1E3	8.3E4
Er-171		0.6	16.2	0.5	13.5	9.0E4	2.4E6
Es-253	Einsteinium(99)*	200	5400	2E-2	5.41E-1		
Es-254		30	811	3E-3	8.11E-2		
Es-254m		0.6	16.2	0.4	10.8		
Es-255							
Eu-147	Europium(63)	2	54.1	2	54.1	1.4E3	3.7E4
Eu-148		0.5	13.5	0.5	13.5	6.0E2	1.6E4
Eu-149		20	541	20	541	3.5E2	9.4E3
Eu-150		0.7	18.9	0.7	18.9	6.1E4	1.6E6
Eu-152m		0.6	16.2	0.5	13.5	8.2E4	2.2E6
Eu-152		0.9	24.3	0.9	24.3	6.5	1.8E2
Eu-154		0.8	21.6	0.5	13.5	9.8	2.6E2
Eu-155		20	541	2	54.1	1.8E1	4.9E2
Eu-156		0.6	16.2	0.5	13.5	2.0E3	5.5E4
F-18	Fluorine(9)	1	27.0	0.5	13.5	3.5E6	9.5E7
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	2.7E5	7.3E6
Fe-55		40	1080	40	1080	8.8E1	2.4E3
Fe-59		0.8	21.6	0.8	21.6	1.8E3	5.0E4
Fe-60		40	1080	0.2	5.41	7.4E-4	2.0E-2
Fm-255	Fermium(100)**	40	1080	0.8	21.6		
Fm-257		10	270	8E-3	2.16E-1		
Ga-67	Gallium(31)	6	162	6	162	2.2E4	6.0E5
Ga-68		0.3	8.11	0.3	8.11	1.5E6	4.1E7
Ga-72		0.4	10.8	0.4	10.8	1.1E5	3.1E6
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	6.9E2	1.9E4

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Gd-148		3	81.1	3E-4	8.11E-3	1.2	3.2E1
Gd-153		10	270	5	135	1.3E2	3.5E3
Gd-159		4	108	0.5	13.5	3.9E4	1.1E6
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	2.6E2	7.1E3
Ge-71		40	1080	40	1080	5.8E3	1.6E5
Ge-77		0.3	8.11	0.3	8.11	1.3E5	3.6E6
H-3	Hydrogen(1)	See T-Tritium					
Hf-172	Hafnium(72)	0.5	13.5	0.3	8.11	4.1E1	1.1E3
Hf-175		3	81.1	3	81.1	3.9E2	1.1E4
Hf-181		2	54.1	0.9	24.3	6.3E2	1.7E4
Hf-182		4	108	3E-2	0.811	8.1E-6	2.2E-4
Hg-194	Mercury(80)	1	27.0	1	27.0	1.3E-1	3.5
Hg-195m		5	135	5	135	1.5E4	4.0E5
Hg-197m		10	270	0.9	24.3	2.5E4	6.7E5
Hg-197		10	270	10	270	9.2E3	2.5E5
Hg-203		4	108	0.9	24.3	5.1E2	1.4E4
Ho-163	Holmium(67)	40	1080	40	1080	2.7	7.6E1
Ho-166m		0.6	16.2	0.3	8.11	6.6E-2	1.8
Ho-166		0.3	8.11	0.3	8.11	2.6E4	7.0E5
I-123	Iodine(53)	6	162	6	162	7.1E4	1.9E6
I-124		0.9	24.3	0.9	24.3	9.3E3	2.5E5
I-125		20	541	2	54.1	6.4E2	1.7E4
I-126		2	54.1	0.9	24.3	2.9E3	8.0E4
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5E-6	1.8E-4
I-131		3	81.1	0.5	13.5	4.6E3	1.2E5
I-132		0.4	10.8	0.4	10.8	3.8E5	1.0E7
I-133		0.6	16.2	0.5	13.5	4.2E4	1.1E6
I-134		0.3	8.11	0.3	8.11	9.9E5	2.7E7
I-135		0.6	16.2	0.5	13.5	1.3E5	3.5E6
In-111	Indium(49)	2	54.1	2	54.1	1.5E4	4.2E5
In-113m		4	108	4	108	6.2E5	1.7E7

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
In-114m		0.3	8.11	0.3	8.11	8.6E2	2.3E4
In-115m		6	162	0.9	24.3	2.2E5	6.1E6
Ir-189	Iridium(77)	10	270	10	270	1.9E3	5.2E4
Ir-190		0.7	18.9	0.7	18.9	2.3E3	6.2E4
Ir-192		1	27.0	0.5	13.5	3.4E2	9.2E3
Ir-193m		10	270	10	270	2.4E3	6.4E4
Ir-194		0.2	5.41	0.2	5.41	3.1E4	8.4E5
K-40	Potassium(19)	0.6	16.2	0.6	16.2	2.4E-7	6.4E-6
K-42		0.2	5.41	0.2	5.41	2.2E5	6.0E6
K-43		1.0	27.0	0.5	13.5	1.2E5	3.3E6
Kr-81	Krypton(36)	40	1080	40	1080	7.8E-4	2.1E-2
Kr-85m		6	162	6	162	3.0E5	8.2E6
Kr-85		20	541	10	270	1.5E1	3.9E2
Kr-87		0.2	5.41	0.2	5.41	1.0E6	2.8E7
La-137	Lanthanum(57)	40	1080	2	54.1	1.6E-3	4.4E-2
La-140		0.4	10.8	0.4	10.8	2.1E4	5.6E5
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	4.2E3	1.1E5
Lu-173		8	216	8	216	5.6E1	1.5E3
Lu-174m		20	541	8	216	2.0E2	5.3E3
Lu-174		8	216	4	108	2.3E1	6.2E2
Lu-177		30	811	0.9	24.3	4.1E3	1.1E5
MFP	For mixed fission products, use formula for mixtures or Table II						
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	2.0E5	5.4E6
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	1.6E4	4.4E5
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8E-5	1.8E-3
Mn-54		1	27.0	1	27.0	2.9E2	7.7E3
Mn-56		0.2	5.41	0.2	5.41	8.0E5	2.2E7
Mo-93	Molybdenum(42)	40	1080	7	189	4.1E-2	1.1
Mo-99		0.6	16.2	0.5	13.5***	1.8E4	4.8E5
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	5.4E7	1.5E9
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	2.3E2	6.3E3

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	(Ci/g)
Na-24		0.2	5.41	0.2	5.41	3.2E5	8.7E6
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	5.2E3	1.4E5
Nb-93m		40	1080	6	162	8.8	2.4E2
Nb-94		0.6	16.2	0.6	16.2	6.9E-3	1.9E-1
Nb-95		1	27.0	1	27.0	1.5E3	3.9E4
Nb-97		0.6	16.2	0.5	13.5	9.9E5	2.7E7
Nd-147	Neodymium(60)	4	108	0.5	13.5	3.0E3	8.1E4
Nd-149		0.6	16.2	0.5	13.5	4.5E5	1.2E7
Ni-59	Nickel(28)	40	1080	40	1080	3.0E-3	8.0E-2
Ni-63		40	1080	30	811	2.1	5.7E1
Ni-65		0.3	8.11	0.3	8.11	7.1E5	1.9E7
Np-235	Neptunium(93)	40	1080	40	1080	5.2E1	1.4E3
Np-236		7	189	1E-3	2.70E-2	4.7E-4	1.3E-2
Np-237		2	54.1	2E-4	5.41E-3	2.6E-5	7.1E-4
Np-239		6	162	0.5	13.5	8.6E3	2.3E5
Os-185	Osmium(76)	1	27.0	1	27.0	2.8E2	7.5E3
Os-191m		40	1080	40	1080	4.6E4	1.3E6
Os-191		10	270	0.9	24.3	1.6E3	4.4E4
Os-193		0.6	16.2	0.5	13.5	2.0E4	5.3E5
Os-194		0.2	5.41	0.2	5.41	1.1E1	3.1E2
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	1.1E4	2.9E5
P-33		40	1080	0.9	24.3	5.8E3	1.6E5
Pa-230	Protactinium(91)	2	54.1	0.1	2.70	1.2E3	3.3E4
Pa-231		0.6	16.2	6E-5	1.62E-3	1.7E-3	4.7E-2
Pa-233		5	135	0.9	24.3	7.7E2	2.1E4
Pb-201	Lead(82)	1	27.0	1	27.0	6.2E4	1.7E6
Pb-202		40	1080	2	54.1	1.2E-4	3.4E-3
Pb-203		3	81.1	3	81.1	1.1E4	3.0E5
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	4.5E-6	1.2E-4
Pb-210		0.6	16.2	9E-3	0.243	2.8	7.6E1
Pb-212		0.3	8.11	0.3	8.11	5.1E4	1.4E6

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Pd-103	Palladium(46)	40	1080	40	1080	2.8E3	7.5E4
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9E-5	5.1E-4
Pd-109		0.6	16.2	0.5	13.5	7.9E4	2.1E6
Pm-143	Promethium(61)	3	81.1	3	81.1	1.3E2	3.4E3
Pm-144		0.6	16.2	0.6	16.2	9.2E1	2.5E3
Pm-145		30	811	7	189	5.2	1.4E2
Pm-147		40	1080	0.9	24.3	3.4E1	9.3E2
Pm-148m		0.5	13.5	0.5	13.5	7.9E2	2.1E4
Pm-149		0.6	16.2	0.5	13.5	1.5E4	4.0E5
Pm-151		3	81.1	0.5	13.5	2.7E4	7.3E5
Po-208	Polonium(84)	40	1080	2E-2	0.541	2.2E1	5.9E2
Po-209		40	1080	2E-2	0.541	6.2E-1	1.7E1
Po-210		40	1080	2E-2	0.541	1.7E2	4.5E3
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	4.3E4	1.2E6
Pr-143		4	108	0.5	13.5	2.5E3	6.7E4
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	2.5E3	6.8E4
Pt-191		3	81.1	3	81.1	8.7E3	2.4E5
Pt-193m		40	1080	9	243	5.8E3	1.6E5
Pt-193		40	1080	40	1080	1.4	3.7E1
Pt-195m		10	270	2	54.1	6.2E3	1.7E5
Pt-197m		10	270	0.9	24.3	3.7E5	1.0E7
Pt-197		20	541	0.5	13.5	3.2E4	8.7E5
Pu-236	Plutonium(94)	7	189	7E-4	1.89E-2	2.0E1	5.3E2
Pu-237		20	541	20	541	4.5E2	1.2E4
Pu-238		2	54.1	2E-4	5.41E-3	6.3E-1	1.7E1
Pu-239		2	54.1	2E-4	5.41E-3	2.3E-3	6.2E-2
Pu-240		2	54.1	2E-4	5.41E-3	8.4E-3	2.3E-1
Pu-241		40	1080	1E-2	0.270	3.8	1.0E2
Pu-242		2	54.1	2E-4	5.41E-3	1.5E-4	3.9E-3
Pu-244		0.3	8.11	2E-4	5.41E-3	6.7E-7	1.8E-5
Ra-223	Radium(88)	0.6	16.2	3E-2	0.811	1.9E3	5.1E4

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	(Ci/g)
Ra-224		0.3	8.11	6E-2	1.62	5.9E3	1.6E5
Ra-225		0.6	16.2	2E-2	0.541	1.5E3	3.9E4
Ra-226		0.3	8.11	2E-2	0.541	3.7E-2	1.0
Ra-228		0.6	16.2	4E-2	1.08	1.0E1	2.7E2
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	3.1E5	8.4E6
Rb-83		2	54.1	2	54.1	6.8E2	1.8E4
Rb-84		1	27.0	0.9	24.3	1.8E3	4.7E4
Rb-86		0.3	8.11	0.3	8.11	3.0E3	8.1E4
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2E-9	8.6E-8
Rb(natural)		Unlimited	Unlimited	Unlimited	Unlimited	6.7E6	1.8E8
Re-183	Rhenium(75)	5	135	5	135	3.8E2	1.0E4
Re-184m		3	81.1	3	81.1	1.6E2	4.3E3
Re-184		1	27.0	1	27.0	6.9E2	1.9E4
Re-186		4	108	0.5	13.5	6.9E3	1.9E5
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4E-9	3.8E-8
Re-188		0.2	5.41	0.2	5.41	3.6E4	9.8E5
Re-189		4	108	0.5	13.5	2.5E4	6.8E5
Re(natural)		Unlimited	Unlimited	Unlimited	Unlimited		2.4E-8
Rh-99	Rhodium(45)	2	54.1	2	54.1	3.0E3	8.2E4
Rh-101		4	108	4	108	4.1E1	1.1E3
Rh-102m		2	54.1	0.9	24.3	2.3E2	6.2E3
Rh-102		0.5	13.5	0.5	13.5	4.5E1	1.2E3
Rh-103m		40	1080	40	1080	1.2E6	3.3E7
Rh-105		10	270	0.9	24.3	3.1E4	8.4E5
Rn-222	Radon(86)	0.2	5.41	4E-3	0.108	5.7E3	1.5E5
Ru-97	Ruthenium(44)	4	108	4	108	1.7E4	4.6E5
Ru-103		2	54.1	0.9	24.3	1.2E3	3.2E4
Ru-105		0.6	16.2	0.5	13.5	2.5E5	6.7E6
Ru-106		0.2	5.41	0.2	5.41	1.2E2	3.3E3
S-35	Sulfur(16)	40	1080	2	54.1	1.6E3	4.3E4
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	1.5E4	4.0E5

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Sb-124		0.6	16.2	0.5	13.5	6.5E2	1.7E4
Sb-125		2	54.1	0.9	24.3	3.9E1	1.0E3
Sb-126		0.4	10.8	0.4	10.8	3.1E3	8.4E4
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	6.7E5	1.8E7
Sc-46		0.5	13.5	0.5	13.5	1.3E3	3.4E4
Sc-47		9	243	0.9	24.3	3.1E4	8.3E5
Sc-48		0.3	8.11	0.3	8.11	5.5E4	1.5E6
Se-75	Selenium(34)	3	81.1	3	81.1	5.4E2	1.5E4
Se-79		40	1080	2	54.1	2.6E-3	7.0E-2
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	1.4E6	3.9E7
Si-32		40	1080	0.2	5.41	3.9	1.1E2
Sm-145	Samarium(62)	20	541	20	541	9.8E1	2.6E3
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5E-1	2.3E-8
Sm-151		40	1080	4	108	9.7E-1	2.6E1
Sm-153		4	108	0.5	13.5	1.6E4	4.4E5
Sn-113	Tin(50)	4	108	4	108	3.7E2	1.0E4
Sn-117m		6	162	2	54.1	3.0E3	8.2E4
Sn-119m		40	1080	40	1080	1.4E2	3.7E3
Sn-121m		40	1080	0.9	24.3	2.0	5.4E1
Sn-123		0.6	16.2	0.5	13.5	3.0E2	8.2E3
Sn-125		0.2	5.41	0.2	5.41	4.0E3	1.1E5
Sn-126		0.3	8.11	0.3	8.11	1.0E-3	2.8E-2
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	2.3E3	6.2E4
Sr-85m		5	135	5	135	1.2E6	3.3E7
Sr-85		2	54.1	2	54.1	8.8E2	2.4E4
Sr-87m		3	81.1	3	81.1	4.8E5	1.3E7
Sr-89		0.6	16.2	0.5	13.5	1.1E3	2.9E4
Sr-90		0.2	5.41	0.1	2.70	5.1	1.4E2
Sr-91		0.3	8.11	0.3	8.11	1.3E5	3.6E6
Sr-92		0.8	21.6	0.5	13.5	4.7E5	1.3E7
T	Tritium(1)	40	1080	40	1080	3.6E2	9.7E3

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ta-178	Tantalum(73)	1	27.0	1	27.0	4.2E6	1.1E8
Ta-179		30	811	30	811	4.1E1	1.1E3
Ta-182		0.8	21.6	0.5	13.5	2.3E2	6.2E3
Tb-157	Terbium(65)	40	1080	10	270	5.6E-1	1.5E1
Tb-158		1	27.0	0.7	18.9	5.6E-1	1.5E1
Tb-160		0.9	24.3	0.5	13.5	4.2E2	1.1E4
Tc-95m	Technetium(43)	2	54.1	2	54.1	8.3E2	2.2E4
Tc-96m		0.4	10.8	0.4	10.8	1.4E6	3.8E7
Tc-96		0.4	10.8	0.4	10.8	1.2E4	3.2E5
Tc-97m		40	1080	40	1080	5.6E2	1.5E4
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2E-5	1.4E-3
Tc-98		0.7	18.9	0.7	18.9	3.2E-5	8.7E-4
Tc-99m		8	216	8	216	1.9E5	5.3E6
Tc-99		40	1080	0.9	24.3	6.3E-4	1.7E-2
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	6.8E3	1.8E5
Te-121m		5	135	5	135	2.6E2	7.0E3
Te-121		2	54.1	2	54.1	2.4E3	6.4E4
Te-123m		7	189	7	189	3.3E2	8.9E3
Te-125m		30	811	9	243	6.7E2	1.8E4
Te-127m		20	541	0.5	13.5	3.5E2	9.4E3
Te-127		20	541	0.5	13.5	9.8E4	2.6E6
Te-129m		0.6	16.2	0.5	13.5	1.1E3	3.0E4
Te-129		0.6	16.2	0.5	13.5	7.7E5	2.1E7
Te-131m		0.7	18.9	0.5	13.5	3.0E4	8.0E5
Te-132		0.4	10.8	0.4	10.8	1.1E4	3.0E5
Th-227	Thorium(90)	9	243	1E-2	0.270	1.1E3	3.1E4
Th-228		0.3	8.11	4E-4	1.08E-2	3.0E1	8.2E2
Th-229		0.3	8.11	3E-5	8.11E-4	7.9E-3	2.1E-1
Th-230		2	54.1	2E-4	5.41E-3	7.6E-4	2.1E-2
Th-231		40	1080	0.9	24.3	2.0E4	5.3E5
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0E-9	1.1E-7

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Th-234		0.2	5.41	0.2	5.41	8.6E2	2.3E4
Th(natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.1E-9	2.2E-7
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4	1.7E2
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	2.2E4	6.0E5
Tl-201		10	270	10	270	7.9E3	2.1E5
Tl-202		2	54.1	2	54.1	2.0E3	5.3E4
Tl-204		4	108	0.5	13.5	1.7E1	4.6E2
Tm-167	Thulium(69)	7	189	7	189	3.1E3	8.5E4
Tm-168		0.8	21.6	0.8	21.6	3.1E2	8.3E3
Tm-170		4	108	0.5	13.5	2.2E2	6.0E3
Tm-171		40	1080	10	270	4.0E1	1.1E3
U-230	Uranium(92)	40	1080	1E-2	0.270	1.0E3	2.7E4
U-232		3	81.1	3E-4	8.11E-3	8.3E-1	2.2E1
U-233		10	270	1E-3	2.70E-2	3.6E-4	9.7E-3
U-234		10	270	1E-3	2.70E-2	2.3E-4	6.2E-3
U-235		Unlimited	Unlimited	Unlimited	Unlimited	8.0E-8	2.2E-6
U-236		10	270	1E-3	2.70E-2	2.4E-6	6.5E-5
U-238		Unlimited	Unlimited	Unlimited	Unlimited	1.2E-8	3.4E-7
U(natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.6E-8	7.1E-7
U(enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited		(See Table A-3)
U(enriched more than 5%)			10	270	1E-3	2.70E-2	(See Table A-3)
U(depleted)		Unlimited	Unlimited	Unlimited	Unlimited		(See Table A-3)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	6.3E3	1.7E5
V-49		40	1080	40	1080	3.0E2	8.1E3
W-178	Tungsten(74)	1	27.0	1	27.0	1.3E3	3.4E4
W-181		30	811	30	811	2.2E2	6.0E3
W-185		40	1080	0.9	24.3	3.5E2	9.4E3
W-187		2	54.1	0.5	13.5	2.6E4	7.0E5

Symbol of Radionuclide	Element and Atomic Number	A_1(TBq)	A_1(Ci)	A_2(TBq)	A_2(Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
W-188		0.2	5.41	0.2	5.41	3.7E2	1.0E4
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	4.8E4	1.3E6
Xe-123		0.2	5.41	0.2	5.41	4.4E5	1.2E7
Xe-127		4	108	4	108	1.0E3	2.8E4
Xe-131m		40	1080	40	1080	3.1E3	8.4E4
Xe-133		20	541	20	541	6.9E3	1.9E5
Xe-135		4	108	4	108	9.5E4	2.6E6
Y-87	Yttrium(39)	2	54.1	2	54.1	1.7E4	4.5E5
Y-88		0.4	10.8	0.4	10.8	5.2E2	1.4E4
Y-90		0.2	5.41	0.2	5.41	2.0E4	5.4E5
Y-91m		2	54.1	2	54.1	1.5E6	4.2E7
Y-91		0.3	8.11	0.3	8.11	9.1E2	2.5E4
Y-92		0.2	5.41	0.2	5.41	3.6E5	9.6E6
Y-93		0.2	5.41	0.2	5.41	1.2E5	3.3E6
Yb-169	Ytterbium(70)	3	81.1	3	81.1	8.9E2	2.4E4
Yb-175		30	811	0.9	24.3	6.6E3	1.8E5
Zn-65	Zinc(30)	2	54.1	2	54.1	3.0E2	8.2E3
Zn-69m		2	54.1	0.5	13.5	1.2E5	3.3E6
Zn-69		4	108	0.5	13.5	1.8E6	4.9E7
Zr-88	Zirconium(40	3	81.1	3	81.1	6.6E2	1.8E4
Zr-93		40	1080	0.2	5.41	9.3E-5	2.5E-3
Zr-95		1	27.0	0.9	24.3	7.9E2	2.1E4
Zr-97		0.3	8.11	0.3	8.11	7.1E4	1.9E6

* International shipments of Einsteinium require multilateral approval of A_1 and A_2 values.
** International shipments of Fermium require multilateral approval of A_1 and A_2 values.
*** 20 Ci for Mo99 for domestic use.

~~Table II~~
~~Relationship Between A_1 and E_{max} for Beta Emitters~~

~~E_{max} (MeV)~~	~~A_1 (Ci)~~
~~< 0.5~~	~~1000~~
~~0.5 - < 1.0~~	~~300~~
~~1.0 - < 1.5~~	~~100~~
~~1.5 - < 2.0~~	~~30~~
~~≥ 2.0~~	~~10~~

Table II
General Values for A_1 and A_2

Contents	A_1		A_2	
	(TBq)	(Ci)	(TBq)	(Ci)
Only beta- or gamma-emitting nuclides are known to be present	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevent data are available	0.10	2.70	$2x10^{-5}$	$5.41x10^{-}$

~~Table III~~

~~Relationship Between A_3 and the Atomic Number of the Radionuclide~~

~~Atomic Number~~	~~A_3~~		
	~~Half-life less than 1000 days~~	~~Half-life greater than 1000 days to 10^6 years~~	~~Half-life greater than 10^6 years~~
~~1 to 81~~	~~3 Ci~~	~~0.05 Ci~~	~~3 Ci~~
~~82 and above~~	~~0.002 Ci~~	~~0.002 Ci~~	~~3 Ci~~

Table ~~IV~~ III

Activity-Mass Relationships for Uranium~~/Thorium~~

~~Thorium and Uranium Enrichment* wt % U-235 present~~	~~Special Activity~~	
	~~Ci/g~~	~~g/Ci~~
~~0.45~~	~~5.0×10^{-7}~~	~~2.0×10^{6}~~
~~0.72 (natural)~~	~~7.06×10^{-7}~~	~~1.42×10^{6}~~
~~1.0~~	~~7.6×10^{-7}~~	~~1.3×10^{6}~~
~~1.5~~	~~1.0×10^{-6}~~	~~1.0×10^{6}~~
~~5.0~~	~~2.7×10^{-6}~~	~~3.7×10^{5}~~
~~10.0~~	~~4.8×10^{-6}~~	~~2.1×10^{5}~~
~~20.0~~	~~1.0×10^{-5}~~	~~1.0×10^{5}~~
~~35.0~~	~~2.0×10^{-5}~~	~~5.0×10^{4}~~
~~50.0~~	~~2.5×10^{-5}~~	~~4.0×10^{4}~~
~~90.0~~	~~5.8×10^{-5}~~	~~1.7×10^{4}~~
~~93.0~~	~~7.0×10^{-5}~~	~~1.4×10^{4}~~
~~95.0~~	~~9.1×10^{-5}~~	~~1.1×10^{4}~~
~~Natural Thorium~~	~~2.2×10^{-7}~~	~~4.6×10^{6}~~

Uranium Enrichment* wt % U-235 present	Specific Activity TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72 (natural)	2.6×10^{-8}	7.1×10^{-7}
1.0	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5.0	1.0×10^{-7}	2.7×10^{-6}
10.0	1.8×10^{-7}	4.8×10^{-6}
20.0	3.7×10^{-7}	1.0×10^{-5}
35.0	7.4×10^{-7}	2.0×10^{-5}
50.0	9.3×10^{-7}	2.5×10^{-5}
90.0	2.2×10^{-6}	5.8×10^{-5}
93.0	2.6×10^{-6}	7.0×10^{-5}
95.0	3.4×10^{-6}	9.1×10^{-5}

*The figures for uranium include representative values for the activity of the uranium-234 which is concentrated during the enrichment process. ~~The activity for thorium includes the equilibrium concentration of thorium-228.~~