CHAPTER 33-10-01
GENERAL PROVISIONS

33-10-01-01. Purpose. It is the purpose of this article to state such requirements as shall be applied in the use of all sources of ionizing radiation within North Dakota. This article provides for the protection of public health and maximum safety to all persons at, or in the vicinity of the place of use and storage of sources of ionizing radiation and in addition with respect to radioactive materials, or devices containing radioactive materials, the disposal thereof. This article is intended to be consistent with the best use of ionizing radiation.

General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-01-02. Scope. Except as otherwise specifically provided, this article applies to all persons who receive, possess, use, transfer, own, or acquire any source of radiation, provided, however, that nothing in this article shall apply to any person to the extent such person is subject to regulation by the United States nuclear regulatory commission. Attention is directed to the fact that regulation by this state of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between this state and the United States nuclear regulatory commission and to part 150 of the commission's regulations (10 CFR part 150).

General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-01-03. Authority. The North Dakota department of health has been authorized to provide and administer this article under the provisions of North Dakota Century Code chapter 23-20.1.

General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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, low specific activity (LSA), and surface contaminated object (SCO) radioactive 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~~1. "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~~2. "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 concentration-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 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 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 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 radiation from radioactive materials regulated by the department.~~

~~14~~3. "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~~4. "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 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~~5. "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~~6. "CFR" means Code of Federal Regulations.

~~21~~7. "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and gluconic acid).

~~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 ($H_{E,50} = \sum W_T H_{T,50}$).~~

~~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~~8. "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).

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

~~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.~~

~~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.~~

~~30~~9. "Department" means the North Dakota department of health.

~~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.~~

~~32~~10. "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.

~~33~~11. "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.

~~34~~12. "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.

~~35. "Effective dose 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 ($H_E = \sum W_T H_T$).~~

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

~~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.~~

~~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.~~

~~39~~13. "Exposure" means being exposed to ionizing radiation or to radioactive material.

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

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

~~42. "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.~~

~~43. "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.~~

~~44~~14. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram [100 rad].

~~45~~15. "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.

~~46~~16. "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.

~~47. "High radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one hundred millirems [1 millisievert] in one hour at thirty centimeters from any source of radiation or from any surface that the radiation penetrates.~~

~~48~~17. "Human use" means the internal or external administration of radiation or radioactive material to human beings.

~~49. "Individual" means any human being.~~

~~50. "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).~~

~~51. "Individual monitoring devices" includes individual monitoring equipment and 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, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.~~

~~52~~18. "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.

~~53. "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.~~

~~54. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.~~

~~55. "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent 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.~~

~~56~~19. "License" means a general or specific license issued by the department in accordance with the regulations adopted by the department.

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

~~58~~20. "Licensee" means any person who is licensed by the department in accordance with this article and North Dakota Century Code chapter 23-20.1.

~~59~~21. "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, inc.

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

~~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.~~

~~63~~22. "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 33-10-07.1.~~

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

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

~~67~~23. "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.

~~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.)~~

~~69~~24. "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).~~

~~71~~25. "Nuclear regulatory commission (NRC)" means the United States nuclear regulatory commission or its duly authorized representatives.

~~72. "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed, unlicensed, registered and unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released in accordance with section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"), from voluntary participation in medical research programs, or as a member of the public.~~

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

~~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.~~

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

~~77~~26. "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.

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

~~79. "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.~~

~~80. "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.~~

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

~~82~~27. "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

~~83. "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with section 33-10-07.1-32 ("release of individuals containing unsealed radioactive material or implants containing radioactive material"), or from voluntary participation in medical research programs.~~

~~84. "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.~~

~~85~~28. "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.

~~86~~29. "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).

~~87~~30. "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.

~~88. "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.~~

~~89. "Radiation dose" (see "dose").~~

~~90~~31. "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 radiation exposure is the coulomb per kilogram (C/kg). (See section 33-10-01-14 units of exposure, dose, and activity for the special unit equivalent "roentgen" (R).)

~~91~~32. "Radiation exposure rate" means the radiation exposure per unit of time, such as R/min, mR/h, etc.

~~92~~33. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

~~93~~34. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

~~94~~35. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

~~95~~36. "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

~~96. "Radiobioassay" (see "bioassay").~~

~~97~~37. "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.

~~98~~38. "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.

~~99~~39. "Regulations of the United States department of transportation" means the regulations in 49 CFR part 100-189.

~~100~~40. "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)).

~~101. "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.~~

~~102. "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 article.~~

~~103. "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 radioactive material. "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.~~

~~104~~41. "Roentgen" (R) means the special unit of exposure. One roentgen equals two hundred fifty-eight millionths of a coulomb per kilogram of air (see "Exposure").

~~105~~42. "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.

~~106. "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of seven one-thousandths centimeter [7 mg/cm^2].~~

~~107~~43. "SI" means the abbreviation for the international system of units.

~~108~~44. "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 rems).

~~109. "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.~~

~~110. "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.~~

~~111~~45. "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.

~~112~~46. "Source material milling" means any activity that results in the production of byproduct material as defined in subdivision b of subsection 17.

~~113~~47. "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~114. "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 designed after March 31, 1996, or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.~~

~~115~~48. "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.

~~116. "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.~~

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

~~117. "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 300 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 300 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 300 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 300 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 300 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.~~

~~118. "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.~~

~~119~~49. "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.

~~120~~50. "These rules" means all parts of this article and any subsequent changes or additions thereto.

~~121. "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.~~

~~122. "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.~~

~~123. "United States department of energy" means the department of energy established by Pub. L. 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).~~

~~124. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.~~

~~125. "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.~~

~~126. "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.~~

~~127~~51. "Uranium fuel cycle" means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered nonuranium special nuclear and byproduct materials from the cycle.

~~128. "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.~~

~~129~~52. "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

~~130. "Week" means seven consecutive days starting on Sunday.~~

~~131. "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.~~

~~132~~53. "Worker" means an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant.

~~133. "Working level" (WL) means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 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.~~

~~134. "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.~~

~~135. "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; March 1, 2003.
General Authority: NDCC 28-32-02, 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-01-05. Exemptions.

1. General provision. The department may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of this article as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

2. United States department of energy contractors and United States nuclear regulatory commission contractors. Any United States

department of energy contractor or subcontractor and any United States nuclear regulatory commission contractor or subcontractor of the following categories operating within this state is exempt from this article to the extent that such contractor or subcontractor under the contractor's or subcontractor's contract receives, possesses, uses, transfers, or acquires sources of radiation:

a. Prime contractors performing work for the United States department of energy at United States government-owned or government-controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation.

b. Prime contractors of the United States department of energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof.

c. Prime contractors of the United States department of energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.

d. Any other prime contractor or subcontractor of the United States department of energy or the nuclear regulatory commission when the state and the nuclear regulatory commission jointly determine (1) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and (2) that, the exemption of the prime contractor or subcontractor is authorized by law.

History: Amended effective October 1, 1982.
General Authority: NDCC 28-32-02, 23-20.1-04
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.3, 23-20.1-04.4

33-10-01-06. Records. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in this article.

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-09.1

33-10-01-07. Inspections.

1. Each licensee and registrant shall afford the department at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

2. Each licensee and registrant shall make available to the department for inspection, upon reasonable notice, records maintained pursuant to this article.

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-01-08. Tests. Each licensee and registrant shall perform upon instructions from the department or shall permit the department to perform such reasonable tests as the department deems appropriate or necessary including, but not limited to, tests of:

1. Sources of radiation.

2. Facilities where sources of radiation are used or stored.

3. Radiation detection and monitoring instruments.

4. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

History: Amended effective June 1, 1986.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04.4

33-10-01-10. Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of North Dakota Century Code chapter 23-20.1 or any rules or order issued thereunder. Any person who violates any provision of North Dakota Century Code chapter 23-20.1 or

any rule or order issued thereunder, and, upon conviction thereof, may be punished as provided by law.

History: Amended effective June 1, 1986.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-07, 23-20.1-10

33-10-01-11. Impounding. Sources of radiation shall be subject to impounding pursuant to North Dakota Century Code section 23-20.1-09.

General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-09

33-10-01-12. Prohibited uses. The following sources of ionizing radiation are prohibited:

1. A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the registry of sealed source and devices or accepted for certification by the United States food and drug administration, center for devices and radiological health.

2. Shoe-fitting fluoroscopic devices shall not be used.

3. Those sources of ionizing radiation when found to be detrimental to health and safety or in violation of this article.

History: Amended effective March 1, 1994.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-08

33-10-01-13. Communications. All communications and reports concerning this article and applications filed thereunder shall be addressed to the department as follows:

~~Shipping~~
~~North Dakota Department of Health~~
~~Division of Air Quality~~
~~1200 Missouri Avenue, Room 304~~
~~Bismarck, ND 58504~~

~~Mailing~~
~~North Dakota Department of Health~~
~~Division of Air Quality~~

~~Box 5520~~
~~Bismarck, ND 58506-5520~~

Mailing & Shipping Address:
North Dakota Department of Health
Division of Air Quality
918 E Divide Avenue, 2nd Floor
Bismarck, ND 58501-1947

Telephone (701)328-5188
Facsimile (FAX) ~~(701)328-5200~~ (701)328-5185
24-hour emergency in-state 800-472-2121; out-of-state (701)328-9921

History: Amended effective June 1, 1986; June 1, 1992; July 1, 1995; March 1, 2003.
General Authority: NDCC 28-32-02, 23-20.1-04
Law Implemented: NDCC 23-20.1-04.3

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 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 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 (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

CHAPTER 33-10-03 REPEALED

CHAPTER 33-10-03.1 ALL NEW

CHAPTER 33-10-03.1
RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

Section
33-10-03.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 30

33-10-03.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 30. 10 Code of Federal Regulations 30.1, 30.2, 30.3, 30.4, 30.7, 30.9, 30.10, 30.11, 30.12, 30.13, 30.14, 30.15, 30.18, 30.19, 30.20, 30.21, 30.31, 30.32, 30.33, 30.34, 30.35, 30.36, 30.37, 30.38, 30.39, 30.41, 30.50, 30.51, 30.52, 30.53, 30.61, 30.62, 30.70, 30.71, 30.72, appendix A through appendix E to part 30 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 30.21(c), 30.34(d), (e)(1), (e)(3) and 30.41(b)(6).

2. Requirements in 10 Code of Federal Regulations 30 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional office" or "administrator of the appropriate regional office" appear in 10 Code of Federal Regulations part 30, substitute the words "North Dakota department of health" except when used in 10 Code of Federal Regulations 30.12, 30.21 (c), 30.34 (h)(1), and 30.50 (c)(1).

4. 10 Code of Federal Regulations 30.7 employee protection also applies to violations of North Dakota Century Code chapters 23-20 and 23-20.1.

5. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

6. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations 30.

7. North Dakota state form number 8414, "notice to employees", must be posted instead of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations 30.

8. North Dakota Department of Health Radioactive Material License replaces NRC form 374, "Byproduct Material License" as specified in 10 Code of Federal Regulations 30.

9. North Dakota state form number 18941 "Certificate: Disposition of Radioactive Material" must be used instead of NRC form 314 as specified in 10 Code of Federal Regulations 30.

10. For references to 10 Code of Federal Regulations part 170, section 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-04.1 REPEALED

CHAPTER 33-10-04.2 ALL NEW

CHAPTER 33-10-04.2
STANDARDS FOR PROTECTION AGAINST RADIATION

33-10-04.2-01. Adoption by reference of several sections in 10 CFR part 20. 10 Code of Federal Regulations 20.1001, 20.1002, 20.1003, 20.1004, 20.1005, 20.1008, 20.1101, 20.1201, 20.1202, 20.1203, 20.1204, 20.1206, 20.1207, 20.1208, 20.1301, 20.1302, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406, 20.1501, 20.1502, 20.1601, 20.1602, 20.1701, 20.1702, 20.1703, 20.1704, 20.1705, 20.1801, 20.1802, 20.1901, 20.1902, 20.1903, 20.1904, 20.1905, 20.1906, 20.2001, 20.2002, 20.2003, 20.2004, 20.2005, 20.2006, 20.2007, 20.2008, 20.2101, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, 20.2302, appendix A through C to part 20, appendix E to part 20 and appendix G to part 20 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference are 20.1905(g), 20.2203 (c), 20.2206(a)(1), (a)(3), (a)(4) and (a)(5).

2. All of the requirements in chapter 33-10-04.2 apply to both licensees and registrants. A reference in 10 CFR part 20 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", a reference to "licensed material(s)" includes "registered source of radiation" and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33-10 and North Dakota Century Code chapter 23-20.1. "Registration" means the notification of the North Dakota Department of Health 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.

3. Where the words "NRC", "Commission", "Administrator of the appropriate NRC Regional Office", "Administrator of the nearest Commission Regional Office" or "NRC Regional office" appear in 10 CFR part 20, substitute the words "North Dakota Department of Health".

4. Requirements in 10 CFR 20 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

5. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

6. North Dakota state form number 19443 "occupational radiation exposure history", must be used instead of NRC form 4 as specified in 10 CFR 20.

7. North Dakota state form number 8416 "current occupational radiation exposure", must be used instead of NRC form 5 as specified in 10 CFR 20.

8. NRC form 748 shall not be used as described in 10 CFR 20.

9. The words "in the Federal Register and" shall be omitted from 10 CFR 20.1405 (b).

History: [Date of Implementation]
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04

33-10-04.2-02. Individuals working with medical fluoroscopic equipment.

1. Each registrant shall provide dose monitoring and shall monitor occupational exposure to ensure compliance for:

   a. Occupational dose limits to adults pursuant to 10 CFR 20.1201.

   b. Occupational dose limits to minors pursuant to 10 CFR 20.1207.

   c. The dose equivalent to an embryo/fetus pursuant to 10 CFR 20.1208.

History: [Date of Implementation]
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04

33-10-04.2-03. Location of Individual Monitoring Devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subdivision a of subsection 2 wear individual monitoring devices as follows:

1. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

2. An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman, pursuant to 10 CFR 20.1208, shall be located at the waist under any protective apron being worn by the woman;

3. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subparagraph a of 10 CFR 20.1201, shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye; and

4. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subparagraph b of 10 CFR 20.1201, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

History: [Date of Implementation]
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04

33-10-04.2-04. Effective dose equivalent determination during medical fluoroscopy.

1. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in subdivision d of this subsection, the effective dose equivalent for external radiation shall be determined as follows:

   a. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation.

   b. When only one individual monitoring device is used and it is located at the neck (collar) outside the

protective apron, and the reported dose exceeds twenty-five percent of the limit specified in 10 CFR 20.1201, the reported deep dose equivalent value multiplied by three-tenths shall be the effective dose equivalent for external radiation.

c. When two individual monitoring devices are worn, one under the protective apron at the waist and the other outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by one and five-tenths and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by four-hundredths.

d. Subdivisions b and c only apply when all of the following conditions are met:

(1) The individual monitoring devices have not been exposed to radiation from radioactive material.

(2) Leaded glasses, a thyroid shield, and a wrap-around protective apron have been worn whenever using the medical fluoroscopic equipment.

(3) The area around the medical fluoroscopic equipment has been equipped with lead shielding or transparent protective barriers for control of scattered radiation.

(4) The medical fluoroscopic procedures have been performed in a way that minimizes beam on time, such as utilizing last image hold.

(5) Users of the medical fluoroscopic equipment must have had formal training in radiation safety and operation of medical fluoroscopic equipment.

(6) Performance of the medical fluoroscopic equipment must be monitored and maintained via a quality assurance program.

(7) Patient and staff radiation exposures from medical fluoroscopic equipment must be monitored and actions taken to correct problems.

History: [Date of Implementation]
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04

33-10-04.2-05. Radiation machine security and prevention of unauthorized use.

1. The registrant shall secure registered radiation machines from unauthorized removal.

2. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

History: [Date of Implementation]
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04

33-10-04.2-06. Radiation machine labels. 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.

History: [Date of Implementation]
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04

CHAPTER 33-10-05 REPEALED

CHAPTER 33-10-05.1 ALL NEW

CHAPTER 33-10-05.1
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Section
33-10-05.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 34

33-10-05.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 34. 10 Code of Federal Regulations 34.1, 34.3, 34.11, 34.13, 34.20, 34.21, 34.23, 34.25, 34.27, 34.29, 34.31, 34.33, 34.35, 34.41, 34.42, 34.43, 34.45, 34.46, 34.47, 34.49, 34.51, 34.53, 34.61, 34.63, 34.65, 34.67, 34.69, 34.71, 34.73, 34.75, 34.79, 34.81, 34.83, 34.85, 34.87, 34.89, 34.101, 34.111 and appendix A to part 34 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. All of the requirements in chapter 33-10-05.1 apply to both licensees and registrants. A reference in 10 Code of Federal Regulations part 34 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33-10 and North Dakota Century Code chapter 23-20.1. "Registration" means the notification of the North Dakota Department of Health 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.

2. Where the words "NRC", "commission", "Nuclear Regulatory Commission", "United States nuclear regulatory commission", "NRC regional administrator", "NRC regional office", "Administrator of the appropriate nuclear regulatory commission's regional office" or "NRC's office of nuclear material safety and safeguards, division of industrial and medical nuclear safety" appear in 10 Code of Federal Regulations part 34, substitute the words "North Dakota department of health".

3. Requirements in 10 Code of Federal Regulations 34 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations 34.

5. For references to 10 Code of Federal Regulations parts 170 and 171, see 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

Chapter 33-10-06
X-RAYS AND IMAGING SYSTEMS IN THE HEALING ARTS

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

History: Amended effective June 1, 1986; June 1, 1992; March 1, 2003.
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. "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.

~~1~~2. "Accessible surface" means ~~the external surface of the enclosure or housing of the radiation-producing machine as provided by the~~

~~manufacturer~~ surface of equipment or of an equipment part that can be touched by persons without the use of a tool.

~~2~~3. "Added filtration" means any filtration which is in addition to the inherent filtration.

4. "Air kerma" means kerma in air (see "kerma")

5. "Air kerma rate" means the air kerma per unit of time.

6. "AKR" means air kerma rate.

~~3~~7. "Allied Health" means occupations of medical personnel who are not physicians and are qualified by special training to undergo cross-training into x-ray as a limited ~~diagnostic~~ x-ray machine operator. Refer to appendix G for qualifying professions.

~~4~~8. "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.)

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

~~5~~10. "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.

~~6~~11. "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.

~~7~~12. "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location or locations a required quantity of radiation (includes devices such as phototimers and ion chambers).

~~8~~13. "Barrier" (see "protective barrier").

~~9~~14. "Beam axis" means ~~a line~~ the axis of rotation of the beam limiting device from the source through the centers of the X-ray fields.

~~10~~15. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the ~~x-ray field~~ useful beam.

16. "Biennium" means a two-year cycle.

~~11~~17. "Board certified" means an individual who has completed an accredited school of medical radiography or chiropractic radiography and has passed a national registry examination.

~~12~~18. Board eligible" means an individual who has obtained eligibility to take a national registry examination in radiologic technology or chiropractic radiologic technology.

~~13~~19. "Bone densitometry system" means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

~~14~~20. "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.

21. "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.

~~15~~22. "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

~~16~~23. "Certified components" means components of X-ray systems which are subject to rules promulgated under the Radiation Control for Health and Safety Act of 1968 [Pub. L. 90-602].

~~17~~24. "Certified system" means any X-ray system which has one or more certified component or components.

25. "CEU" (see "continuing education unit").

26. "CFR" means Code of Federal Regulations.

~~18~~27. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

~~19~~28. "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a set of observations. It is estimated using the following equation:

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

where:

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample.

~~20~~29. "Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

~~21~~30. "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.

31. "Continuing education" means a planned, organized, and administered learning activity that enhances the knowledge and underlying skills of an x-ray operator.

32. "Continuing education unit" means a unit of measure for continuing education. One CEU is equal to one contact hour.

~~22~~33. "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.

~~23~~34. "Cooling curve" means the graphical relationship between heat units stored and cooling time.

~~24~~35. "CT" (see "computed tomography").

~~25~~36. "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.

37. "Department" means the North Dakota department of health.

~~26~~39. "Detector" (see "radiation detector").

~~27~~40. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

~~28~~41. "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.

~~29~~42. "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.

~~30~~43. "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "scattered radiation").

~~31~~44. "Direct supervision" requires direct observation and observer must be in the room during the time the X-ray image is obtained.

45. "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.

46. "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules.

~~32~~47. "Entrance 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.

~~33~~48. "Equipment" (see "X-ray equipment").

49. "Exposure" means being exposed to ionizing radiation.

~~34~~50. "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.

~~35~~51. "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

~~36~~52. "Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visible 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.

~~37~~53. "Focal spot" means the ~~area~~ location projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

~~38~~54. "General diagnostic operator" means an individual who is American registry of radiologic technologists (ARRT) or American chiropractic registry of radiologic technologists (ACRRT) board-certified, is or has been board-eligible, or has the equivalent educational and clinical training and received specific authorization from the department.

~~39~~55. "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.

~~40~~56. "Gonad shield" means a protective barrier for the testes or ovaries.

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

~~41~~58. "Half-value layer" means the thickness of specified material which attenuates ~~the beam of radiation to~~ X-radiation or gamma radiation to an extent such that the ~~radiation exposure~~ air kerma rate, exposure rate or absorbed dose 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.~~ the value measured without the material at the same point.

59. "Hand held dental x-ray equipment" (see "x-ray equipment").

60. "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 assocaited specialties, dentistry, veterinary medicine, osteopathy, chiropractic and podiatry.

~~42~~61. "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.

~~43~~62. "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.

~~44~~63. "HVL" (see "half-value layer").

~~45~~64. "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.

~~46~~65. "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.

~~47~~66. "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during a mammographic examination.

~~48~~67. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

68. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, requirements and conditions of the department.

~~49~~69. "Irradiation" means the exposure of matter to ionizing radiation.

70. "Kerma" means the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles per unit mass of a specified material. The SI unit of measure is joule per kilogram, or gray (Gy).

~~50~~71. "Kilovolts peak" (see "peak tube potential").

~~51~~72. "kV" means kilovolts.

~~52~~73. "kVp" (see "peak tube potential").

~~53~~74. "kWs" means kilowatt second. It is equivalent to 10^3 kV·mA·s, i.e.,

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

~~54~~75. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

~~55~~76. "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

a. The useful beam; and

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

~~56~~77. "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.

~~57~~78. "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.~~ the area illuminated by light, simulating the radiation field.

~~58~~79. "Limited ~~diagnostic~~ x-ray machine operator" means any individual who has completed the necessary didactic and clinical training required to perform limited scope X-ray procedures.

~~59~~80. "Linear attenuation coefficient" or "μ" 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.

~~60~~81. "mA" means milliampere.

~~61~~82. "mAs" means milliampere second.

~~62~~83. "Milliampere" as used in this chapter applies to X-ray tube current.

~~63~~84. "Milliampere second" as used in this chapter is the product of the tube current and X-ray exposure time measured in seconds.

~~64~~85. "Mobile X-ray equipment" (see "X-ray equipment").

86. "Monitoring" means the measurement of radiation and the use of the measured results to evaluate potential exposures and doses.

~~65~~87. "Patient" means an individual or animal subjected to ~~healing arts examination,~~ radiation for the purposes of diagnosis, or treatment.

~~66~~88. "PBL" means "positive beam limitation".

~~67~~89. "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

~~68~~90. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the ~~attenuation~~ absorption and scattering of the ionizing radiation in question. ~~This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.~~

~~69~~91. "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").

92. "Physician" means a medical doctor, doctor of osteopathy, doctor of podiatry or chiropractor licensed by state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico.

~~70. "PID" has the same meaning as "position indicating device".~~

~~71~~93. "Portable X-ray equipment" (see "X-ray equipment").

~~72~~94. "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.

~~73~~95. "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.

~~74~~96. "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~~ delivered.

~~75~~97. "Primary protective barrier" (see "protective barrier").

~~76~~98. "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

~~77~~99. "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; and

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

~~78~~100. "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

~~79~~101. "Qualified expert" means an individual having the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American board of radiology, or the American board of health physics, or the American board of medical physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, "qualified expert" means an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in therapeutic radiological physics or X-ray and radium physics by the American board of radiology, or those having equivalent qualifications.

102. "Radiation" means X-rays and gamma rays, which are capable of producing ions. For purposes of this chapter, ionizing radiation is an equivalent term.

~~80~~103. "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.

104. "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 radiation exposure is the coulomb per kilogram (C/kg). (See section 33-10-01-14 units of exposure, dose, and activity for the special unit equivalent "roentgen" (R).)

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

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

~~81~~107. "Radiation therapy simulation system" means a radiographic, ~~or~~ fluoroscopic, or computed tomography 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.

~~82~~108. "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.

~~83~~109. "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

~~84~~110. "Radiological physicist" means an individual who:

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

b. Has a bachelor's degree in, one of the physical sciences or engineering and three years full-time experience working in therapeutic or diagnostic 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 or diagnostic 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.

~~85~~111. "Rating" means the operating limits as specified by the component manufacturer.

~~86~~112. "Recording" means producing a permanent form of an image resulting from X-ray photons.

113. "Registrant" means any person, group or facility who is registered with the department and is legally obligated to register with the department pursuant to the North Dakota Century Code chapter 23-20-1.

114. "Roentgen" (R) means the special unit of exposure. One roentgen equals two hundred fifty-eight millionth of a coulomb per kilograph of air.

~~87~~115. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (see "direct scattered radiation").

~~88~~116. "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

~~89~~117. "Secondary protective barrier" (see "protective barrier").

~~90~~118. "Shutter" means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

119. "SI" means the abbreviation for the international system of units.

~~91~~120. "SID" (see "source-image receptor distance").

~~92~~121. "Source" means the ~~focal spot of the X-ray tube~~ location and/or material from which the radiation emanates.

~~93~~122. "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

~~94~~123. "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

~~95~~124. "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

~~96~~125. "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.

~~97. "SSD" means the distance between the source and the skin entrance plane of the patient.~~

~~98~~126. "Stationary X-ray equipment" (see "X-ray equipment").

~~99~~127. "Stray radiation" means the sum of leakage and scattered radiation.

128. "Survey" means an evaluation of the radiological conditions which may include tests, physical examinations and measurements of levels of radiation.

~~100~~129. "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 mA, 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 mAs.

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 kilovolts and either tube current in milliampere and exposure time in seconds, or the product of tube current and exposure time in milliampere second.

~~101~~130. "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.

~~102~~131. "Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

~~103~~132. "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.

~~104~~133. "Tube" means an X-ray tube, unless otherwise specified.

~~105~~134. "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.

~~106~~135. "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

~~107~~136. "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.

~~108~~137. "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.

~~109~~138. "Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

~~110~~139. "Wedge filter" means an added filter effecting continuous progressive attenuation on all or a part of the useful beam.

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

~~111~~141. "X-ray exposure control" means a device, switch, button, or other similar means by which the operator initiates or terminates, or both, the radiation exposure. It may include equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices.

~~112~~142. "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.

d. "Hand held dental X-ray equipment" means any dental X-ray equipment which is designed to be physically held during X-ray exposure.

~~113~~143. "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.

~~114~~144. "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.

~~115~~145. "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.

~~116~~146. "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into X-ray energy.

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General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-03. General requirements.

1. **Administrative Controls.**

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

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

(2) All individuals, except those listed in part 1 of Appendix G, prior to 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 outlined in Appendix F. In addition, all individuals shall meet the specific requirements as outlined in subparagraphs a or b of this paragraph. The Department may use interview, observation, or testing to determine compliance. Records must be maintained by the registrant to demonstrate compliance with this paragraph.

(a) General diagnostic operators are not limited in scope of practice. Obtaining general diagnostic operator status will consist of one of the following:

[1] Obtain board eligibility or board certification with the American registry of radiologic technologists (ARRT);

[2] Obtain board eligibility or board certification with the American chiropractic registry of radiologic technologists (ACRRT) and only perform X-ray examinations for chiropractic services;

[3] Receive department approval, through individual consideration, by demonstration of an acceptable level of education and clinical training; or

[4] Demonstrate current enrollment in an educational program accredited by a process acceptable to the Department, and provide documentation of competency in all routine radiographic procedures and specialty views.

(b) Limited ~~diagnostic~~ x-ray machine operators are limited in scope of practice to only those procedures listed in Appendix I, except as allowed in subparagraph (c). Limited ~~diagnostic~~ x-ray machine operators must meet the prerequisite qualifications, receive training, and demonstrate competence as follows:

[1] Limited ~~diagnostic~~ x-ray machine operators shall have successfully completed the course of training required by one of the Allied Health Professions listed in part 2 of Appendix G;

[2] Complete at least eighty hours of didactic instruction at a single training program providing didactic instruction in accordance with part 1 of Appendix H;

[3] Complete the three-hour self-study course designed by the State Health Department; and

[4] Complete the clinical experience requirements in part 2 of Appendix H.

(c) Limited ~~diagnostic~~ x-ray machine operators may only conduct diagnostic X-ray examinations outside the scope of practice of Appendix I in accordance with the following:

[1] When it is determined to be an emergency and ordered by individuals listed in part 3 of Appendix G. The individual requesting the procedures must comply with subitems a, b and c.

[a] The requesting individual must provide a written order specifying what types of diagnostic X-ray examinations outside the scope of procedures listed in Appendix I are requested. The order shall contain an explanation of the emergency nature or medical reason for the order.

[b] The requesting individual must provide direct supervision during the time the X-ray image is obtained.

[c] The facility must keep records of all emergency x-ray procedures ordered under this subparagraph.

[2] When a practice requires a specific view or examination outside the scope of practice listed in Appendix I to be conducted on a routine basis, and the facility has only limited ~~diagnostic~~ x-ray machine operators, application may be made to the Department requesting approval for a limited ~~diagnostic~~ x-ray machine operator to perform the procedure. This allowance shall be limited to the facility, the specific individual, and the procedure requested. After an allowance has been granted, re-application and reauthorization are not necessary for the same

procedure. The application for allowance should include the following:

[a] Documentation which demonstrates the need for the specific view;

[b] Documentation on forms supplied by the Department indicating that each individual for which the request is made has demonstrated competence in the procedure; and

[c] Proof of additional didactic instruction or completion of examination as deemed necessary by the Department for each individual.

[3] When it is not a computed tomography exam.

(d) Limited ~~diagnostic~~ x-ray machine operator implementation period.

[1] Individuals who begin taking X-rays after one year from ~~the effective date of this regulation~~ March 1, 2003 will have to meet all of the requirements of this paragraph before operating the X-ray system.

~~[2] Individuals who have completed the training and experience requirements in effect prior to the effective date of this regulation and have been actively working as an X-ray operator for six months, but less than two years, prior to the effective date of this regulation,~~

~~[a] Are exempt from the requirements of items 1 and 4 of subparagraph b; and~~

~~[b] Must complete the eighty-three hours of didactic training in items 2 and 3 of subparagraph b within three years from the effective date of this regulation. Individuals who have previously completed eighty or more hours of acceptable training will not need to retake the eighty-hour training, but, within the three years, must still take the three-hour self study course designed by the State Health Department.~~

~~[3] Individuals who have completed the training and experience requirements in effect prior to the effective date of this regulation and have been actively working as an X-ray operator for more than two years prior to the effective date of this regulation, are exempt from the requirements of items 1 and 4 of subparagraph b and:~~

~~[a] Must complete the requirements of subitem b of item 2; or~~

~~[b] Demonstrate that they have completed at least 80 hours of instruction related to X-ray operations at various training programs and complete the three-hour self study course designed by the State Health Department and demonstrate competence in accordance with appendix K within six months of the effective date of this regulation.~~

~~[4] Individuals who have not been taking X-rays within the six months prior to the effective date of this rule and begin to take X-rays within one year after the effective date of this rule will have to meet the prerequisite qualifications of Appendix G, Part 2 and will have until one year after they begin taking X-rays to complete the training requirements of this paragraph. During this one year period, the individuals should comply with the facilities X-ray operator training requirements in place prior to the effective date of this rule.~~

(3) General diagnostic and limited diagnostic X-ray operators shall maintain continuing education units as outlined in appendix K.

(~~3~~4) 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~~5) 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~~6) Except for human patients who cannot be moved out of the room, only the staff and ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

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

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

(c) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than twenty-five one-hundredths millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

(~~6~~7) Gonad shielding of not less than five-tenths millimeter lead equivalent material must be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(~~7~~8) 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~~9) 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~~10) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:

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

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

(c) Proper film handling and processing procedures.

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

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

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

(f) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

[1] Be positioned properly, for example, tube side facing the right direction and grid centered to the central ray; and

[2] If the grid is of the focused type, be of the proper focal distance for the source image distances being used.

(~~10~~11) 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"~~ 33-10-04.2-01 (10 CFR 20.1201, 20.1207, 20.1208). 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~~ section 33-10-04.2-01 (10 CFR 20.2206). 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~~12) 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. 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 major components and user's manuals for those components.

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

(4) Tube rating charts and cooling curves.

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

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

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

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

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

c. X-ray log.

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

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

2. **Plan review.**

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

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 section ~~33-10-04.1-06 and section 33-10-04.1-07~~ 33-10-04.2-01 (10 CFR 20.1201, 20.1207, 20.1208 and 20.1301).

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994, July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
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 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 In Millimeters Aluminum		
		Dental Intraoral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980	~~All Other~~ Diagnostic X-Ray Systems Manufactured Prior to June 10, 2006	Diagnostic X-ray Systems Manufactured on or After June 10, 2006
Below 51	30	N/A	0.3	0.3
	40	N/A	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

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

for each exposure maximum quantity of charge per exposure.

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

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

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

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

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

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

8. **Technique indicators.**

a. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic ~~radiation~~ 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 operator's position except in the case of spot films made by the fluoroscopist.

9. **Maintaining compliance.** 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. **Locks.** 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 June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

1. **Limitation of useful beam.**

   a. Primary barrier.

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

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

   b. X-ray field.

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

      (2) For uncertified fluoroscopic systems with a spot-film device, the X-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot-film size for which the device is designed. Measurements shall be made at the maximum

source image distance available but at no less than twenty centimeters tabletop to the film plane distance.

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

(4) Other requirements for fluoroscopic beam limitation:

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

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

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

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

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

(a) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot

film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

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

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

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

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

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

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

(b) Must incorporate a signal visible at the fluoroscopist's position which will indicate

whenever the automatic field size adjustment is overridden.

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

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

2. **Activation of the fluoroscopic tube.** X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure or exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. **Radiation exposure rate limits.**

a. Entrance exposure rate allowable limits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) If the source is above the table, the radiation exposure rate shall be measured at thirty

centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(d) In a C-arm type of fluoroscope, both stationary and mobile units shall meet the entrance exposure rate limits specified in paragraphs 1, 2, and 3 of subdivision a of subsection 3, shall be measured thirty centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available source-image receptor distance provided that the end of the spacer assembly or beam-limiting device is not closer than thirty centimeters from the input surface of the fluoroscopic imaging assembly.

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

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

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

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

(c) Conditions of periodic measurements of typical entrance 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 settings typical of clinical use on a twenty-three centimeters thick abdominal patient.

[3] The X-ray systems that incorporate automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage and kilovoltage, or both, to satisfy the conditions of item 2.

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

(d) Conditions of periodic measurements of maximum entrance 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 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.

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

4. **Barrier transmitted radiation rate limits.**

a. The radiation exposure rate due to transmission through the primary protective barrier with the attenuation block in the

useful beam, combined with radiation from the image intensifier, shall not exceed five hundred sixteen thousandths microcoulomb per kilogram [2 milliroentgens] per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen (C/kg) per minute of entrance exposure rate.

b. Measuring compliance of barrier transmission.

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

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

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

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

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

6. **Indication of air kerma rate and cumulative air kerma.** Machines manufactured on or after June 10, 2006, shall provide displays of values of air kerma rate and cumulative air kerma and shall be viewable from the X-ray operator position.

a. When the X-ray tube is activated and the number of images produced per unit time is greater than six images per second, the air kerma rate in mGy/minute shall be continuously displayed and updated at least once every second.

b. The cumulative air kerma in units of mGy shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

c. The display of the air kerma rate shall be clearly distinguishable from the display of the cumulative air kerma.

d. The air kerma rate and cumulative air kerma shall represent the value of conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

(1) For fluoroscopies with X-ray source below the X-ray table, X-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in subparagraphs 33-10-05.3(3)(b), (c) and (e) for measuring compliance with air kerma rate limits.

(2) For C-arm fluoroscopies, the reference location shall be fifteen cm from the isocenter toward the X-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the X-ray beam with the patient's skin.

e. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

f. The displayed air kerma rate and cumulative air kerma shall not deviate from the actual values by more than plus or minus thirty-five percent over the range of six mGy/minute (0.6 R/min) and one hundred mGy (10 R) to the maximum indication of air kerma rate and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three seconds.

~~6~~7. **Source-skin distance.** The source to skin distance shall not be less than:

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

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

c. Thirty centimeters on all mobile fluoroscopes.

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

~~7~~8. **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~~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, 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~~10. **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~~11. **Radiation therapy simulation system.** Radiation therapy simulation systems shall be exempt from all the requirements of subsections 1, 3, 4, and ~~7~~8 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~~8 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~~12. **Structural shielding requirements** (see appendix E).

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

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

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

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

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

      (3) The department may grant an exemption to paragraphs 1 and 2 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; and

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

b. Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of subdivision a, 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 distances 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. 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 shall be the maximum source-image receptor distance for which beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

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

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

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

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

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

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and source-

image receptor distance for which each aperture is designed and shall indicate which aperture is in position for use.

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

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

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

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

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

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

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 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 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". 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.

(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; and

(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 feet] high protection barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least two and seventh-tenths meters [9 feet] from the tube housing assembly during exposures.

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

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

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

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

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

8. **mA/mAs linearity.** The following requirements apply when the equipment is operated on a power supply as specified by the

manufacturer for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rated:

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

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

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 consecutive mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provided continuous selection.

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

9. **Other requirements:**

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

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

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

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20-04, 23-20.1-03, 23-20.1-04

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

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

   a. Eighteen centimeters if operable above fifty kilovolts peak.

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

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

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

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

3. **Radiation exposure control.**

a. Exposure initiation.

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

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

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

c. Exposure termination.

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

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

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

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

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

where X_1 and X_2 are the average values.

e. Exposure control location and operator protection.

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

protected area during the entire exposure and so the operator can view the patient while making the 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.

(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.

(3) Hand held dental X-ray equipment:

(a) Operators shall use all safety devices and follow safety procedures according to the manufacturer.

(b) Operators shall wear a protective apron during exposure in accordance with 33-10-06.1.a(6)(b).

(c) Operators shall have dose monitoring in accordance with 33-10-04.2-01 (10 CFR 20.1502).

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 two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

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

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

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

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

9. **Administrative controls.**

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

b. The tube housing and the position indicating device shall not be hand-held during an exposure unless the system was specifically designed as a hand held dental X-ray machine.

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.

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

e. Security for portable dental systems. A means shall be provided to prevent unauthorized use whenever the X-ray system is not under the control and constant surveillance of the registrant or an authorized operator.

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

History: Amended effective June 1, 1986; June 1, 1992; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

~~1. **Equipment requirements.**~~

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

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

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

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

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

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

c. Removable and adjustable beam-limiting devices.

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

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

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

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

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

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

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

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

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

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

h. Beam monitor system. Systems of greater than one hundred fifty kilovolts peak manufactured after 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 value of radiation exposure 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 at 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 alternative 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 is opened while the X-ray tube is activated, the radiation exposure at a distance of one meter from the source shall be reduced to less than twenty-five and eight tenths microcoulomb per kilogram [100 milliroentgens] per hour.~~

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

~~a. Surveys.~~

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

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

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

~~b. Calibration.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~subdivision b of subsection 3 of section 33-10-06-08 shall be stated.~~

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

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

~~(6) Records of spot check measurement 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 and paragraph 4 of subdivision c have been met.~~

~~**History:** Amended effective June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.~~
~~**General Authority:** NDCC 23-20.1-04~~
~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

33-10-06-09. X-ray and electron therapy systems with energies of one megaelectronvolt (MeV) and above. Repealed effective ~~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 monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.~~

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

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

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

(2) Existing equipment shall meet the following requirements.

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

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

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

(1) The absorbed dose in grays [rads] due to leakage radiation, except in the area specified in subparagraph a of paragraph 1 of subdivision a, when measured at any point one meter from the path of charged particle, before the charged particle strikes the target or window, may not exceed one-tenth percent for X-ray leakage nor five hundredths percent for neutron leakage of the maximum absorbed dose in grays [rads] of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in subparagraph a of paragraph 1 of subdivision a.

(2) The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in paragraph 1 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 values 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 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 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;

(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.

(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 pre selected 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 insure 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 insure 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.

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 systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel.

(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 makes 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 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 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.

(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 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 have been met.

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04

~~**Law Implemented:** NDCC 23-20.1-03, 23-20.1-04~~

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

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

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

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

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

   where:

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

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

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

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

   where:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

μ_w

where:

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

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

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

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

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

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

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

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

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

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

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

2. **Requirements for equipment.**

a. Termination of exposure.

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

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

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

b. Tomographic plane indication and alignment.

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

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

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

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

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

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

d. Indication of computed tomography conditions of operation. The computed tomography X-ray system must be designed such that the computed tomography conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence. On equipment

having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of computed tomography conditions of operation must be visible from any position from which scan initiation is possible.

e. Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port may not exceed that permitted by subsection 3 of section 33-10-06-04.

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

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

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

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

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

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

h. Facility design requirements.

(1) All CT capable systems shall be required to have the X-ray control permanently mounted in a protected area during the entire exposure (see Appendix B).

(2) 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 must 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.

(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 must 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 phantom(s) 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; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-12. Bone densitometry.

1. Bone densitometry systems shall be:

   a. Certified by the manufacturer pursuant to the Medical Device Act and subchapter C - electronic product radiation control (EPRC) of chapter V of the Federal Food, Drug and Cosmetic Act;

   b. Registered in accordance with chapter 33-10-02 of these regulations; and

   c. Maintained and operated in accordance with the manufacturer's specifications.

2. Equipment requirements. Systems with stepless collimators 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 two percent of the source-image receptor distance.

3. Operators of bone densitometry systems shall: Complete a training course on the bone densitometry which is acceptable to the department. The training course shall include:

   a. Basic radiation protection;

b. Operating procedures for bone densitometry systems, to include use of various system functions, safety, and maintenance; and

c. Patient positioning for the type of examinations performed.

4. During the operation of any bone densitometry system:

a. The operator, ancillary personnel, and members of the general public shall be positioned as far away as practical but not less than two meters from the patient and bone densitometry system during the examination.

b. The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

5. The registrant shall keep maintenance records for bone densitometry systems as prescribed by subdivision b of subsection 1 of section 33-10-06-03. These records shall be maintained for inspection by the ~~agency [insert agency recordkeeping timeliness as appropriate]~~ department.

6. Bone densitometry on human patients shall be conducted only:

a. Under a prescription of a licensed practitioner of the healing arts; or

b. Under a screening program approved by the department.

7. Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in appendix E.

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

APPENDIX A
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

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

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

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

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

    c. The dimensions of the room or rooms concerned.

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

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

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

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

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

History: Amended effective June 1, 1992.

APPENDIX B

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

1. Space requirements.

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

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

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

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

2. Structural requirements:

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

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

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

3. X-ray control placement.

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

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

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

4. Viewing system requirements.

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

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

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

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

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

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

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

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

d. When the viewing system is by electronic means:

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

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

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

APPENDIX C
STRUCTURAL SHIELDING REQUIREMENTS

1. General requirements.

   a. Each installation must be provided with such primary or secondary barriers as are necessary to assure compliance with ~~section 33-10-04.1-06 and section 33-10-04.1-07~~ 33-10-04.2-01 (10 CFR 20.1201, 20.1207, 20.1208, 20.1301). This requirement must be deemed to be met if the thicknesses of such barriers are equivalent to those as computed in accordance with Appendices B, C, and D of the National Council on Radiation Protection and Measurements Report No. 49, "Medical X-ray and Gamma-Ray Protection For Energies Up to 10 MeV," modified to meet current dose limits.

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

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

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

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

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

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

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

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

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

c. The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

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

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

4. Intraoral dental radiographic systems.

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

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

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

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

6. Veterinary medicine radiographic installations.

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

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

APPENDIX D
X-RAY FILM DEVELOPING

Time Temperature Chart

Thermometer Readings (Degrees)			Minimum Developing Times (Minutes)
C		F	
27	-	80	2
		79	2
		78	2 ½
		77	2 ½
24	-	76	3
		75	3
		74	3 ½
		73	3 ½
22	-	72	4
		71	4
		70	4 ½
		69	4 ½
20	-	68	5
		67	5 ½
		66	5 ½
		65	6
18	-	64	6 ½
		63	7
		62	8
		61	8 ½
16	-	60	9 ½

Processing of Film

1. Manual processing of film.

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

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

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

(1) The actual temperature of the developer.

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

2. Automatic processors and other closed processing systems.

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

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

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

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

3. Processing deviations from the requirements of appendix D shall be documented by the registrant in

such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

4. Other Requirements:

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

   b. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX F
GENERAL TRAINING
REQUIREMENTS FOR ALL X-RAY OPERATORS

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

1. Fundamentals of radiation safety.

   a. Characteristics of X-radiation.
   b. Units of radiation dose (mrem).
   c. Hazards of exposure to radiation.
   d. Levels of radiation from sources of radiation.
   e. Methods of controlling radiation dose.

      (1) Working time.
      (2) Working distance.
      (3) Shielding.
      (4) Collimation.
      (5) Filtration.
      (6) Gonad shielding and other patient protection devices.
      (7) Restriction of X-ray beam to the image receptor.
      (8) Grid utilization.
      (9) Utilization of mechanical immobilization device.

2. Familiarization with equipment.

   a. Identification of controls.
   b. Function of each control.
   c. How to use a technique chart.

3. Film processing.

   a. Film speed as related to patient exposure.
   b. Film processing parameters.
   c. Quality assurance program.

4. Emergency procedures.

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

5. Proper use of personnel dosimetry.

   a. Location of dosimeter.
   b. Interpretation of personnel monitoring reports.

6. Anatomy and positioning.

   a. Relevant human anatomy.
   b. Relevant human physiology.
   c. Radiographic positioning.

7. The requirements of pertinent federal and state rules.

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

APPENDIX G

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

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

    a. Medical doctors
    b. Chiropractors
    c. Doctors of Osteopathy
    d. Podiatrists

2. Prerequisite Qualification: Individuals who qualify for cross-training as a limited ~~diagnostic~~ x-ray machine operator.

    a. Nurse Practitioner, Registered Nurse, Licensed Practical Nurse, Associate of Science Practical Nurse
    b. Emergency Medical Technician Paramedic
    c. Physical Therapist, Physical Therapy Assistant
    d. Occupational Therapist, Occupational Therapy Assistant
    e. Medical Technologist, Medical Lab Technician, Clinical Lab Technician
    f. Physician Assistant
    g. Orthopedic Physician Assistant

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

    a. Medical Doctor
    b. Doctor of Osteopathy
    c. Physician Assistant
    d. Nurse Practitioner
    e. Chiropractor

APPENDIX H

Limited ~~Diagnostic~~ X-ray Machine Operator Training Requirements

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

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

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

    a. Basic X-ray Physics 12 hrs.
        - general description of production of X-rays
        - function of filtration and effects it has on X-ray beam
        - collimation
        - types and function of beam limiting devices
        - design, features and function of X-ray tube
    b. Radiobiology 1 hr.
        - effects of ionizing radiation to the human body
        - factors that cause somatic and genetic damage
    c. Radiation Protection 6 hrs.
        - ALARA concept
        - shielding materials
        - radiation quantity and units of measurement
        - basic interactions of X-ray with matter
        - primary and secondary scatter

- importance of time, distance, shielding
- maximum permissible dose-occupational/public
- latency period
- patient protection

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

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

f. Anatomy and Positioning

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

g. Pediatric 2 hrs.

h. Rules and Regulations 1 hr.

2. Clinical experience/supervision section. Individuals must complete either a or b below. If the individual is unable to demonstrate clinical competence in a procedure due to a lack of opportunity, the student shall complete the three prerequisite examinations required by Appendix J using simulation for subdivision s a through k subsection 1 of Appendix J. Final demonstration of competence in subdivisions a through s of subsection 1 of Appendix J should be completed as soon as there is a patient requiring the procedure. No individual may perform an unsupervised procedure for which they have not

successfully completed the final demonstration of competence.

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

(1) Direct supervision and evaluation of competence shall be performed by a general diagnostic operator or a limited ~~diagnostic~~ x-ray machine operator with 2 years experience.

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

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

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

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

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

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

(4) Upon completion of one hundred twenty clinical hours and demonstration of competence in

accordance with appendix J for limited ~~diagnostic~~ x-ray machine operator examinations:

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

(b) During the three-month probationary training, a general diagnostic operator, or a limited ~~diagnostic~~ x-ray machine operator with two years experience, or a radiologist must evaluate all films and conduct at least six hours of direct supervision on a weekly basis and give feedback on any needed improvements.

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

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

APPENDIX I

Specific examinations that are allowed in the scope of practice for limited ~~diagnostic~~ x-ray machine operators.

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

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

APPENDIX J

X-ray Procedure and Image Competency Criteria

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

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

    a. Select appropriate film size
    b. Select appropriate technique
    c. Use correct source-to-image distance
    d. Establish proper direction of central ray
    e. Execute proper patient position
    f. Collimate if appropriate
    g. Provide gonadal shielding if appropriate
    h. Use correct film markers
    I. Give proper patient instruction
    j. Place patient information correctly on the film
    k. Complete examination in an acceptable time limit
    l. All anatomical parts included on the film
    m. Correct positioning of anatomical parts
    n. Appropriate contrast
    o. Adequate density
    p. Correct use of right and left markers
    q. Proper accessory markers as needed
    r. No visible motion
    s. Patient information correct and clearly visible

2. If the individual is unable to demonstrate clinical competence while completing the requirements for clinical supervision in either subdivision a or b of subsection 2

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

~~APPENDIX K~~

~~**Training exemption and demonstration of competence for individuals with greater than two years experience**~~

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

~~1. Training exemption~~

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

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

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

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

APPENDIX K

Continuing Education Requirements

Continuing education units (CEU's) are required for all limited X-ray machine operators and general diagnostic operators as defined by 33-10-06-03 of the North Dakota Radiological Health Rules. CEU requirements will be associated with a two-year cycle (biennium).

1. General diagnostic operators shall obtain a minimum of 24 CEU's per biennium.

2. Limited X-ray machine operators shall obtain a minimum of 12 CEU's per biennium.

3. Units from one biennium cannot be carried forward or applied to the following biennium.

4. Determining the beginning of a biennium.

   a. For limited X-ray machine operators and general diagnostic operators not certified through an accrediting body, the biennium will begin January 1, 2009.

   b. For general diagnostic operators certified through an accrediting body, the biennium will be defined by the registration requirements through their accrediting body and shall begin on the first due date following January 1, 2009.

5. CEU activities must be approved by an accrediting body.

CHAPTER 33-10-07.1 REPEALED

CHAPTER 33-10-07.2 ALL NEW

CHAPTER 33-10-07.2
MEDICAL USE OF BYPRODUCT MATERIAL

33-10-07.2-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 35. 10 Code of Federal Regulations 35.1, 35.2, 35.5, 35.6, 35.7, 35.10, 35.11, 35.12, 35.13, 35.14, 35.15, 35.18, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.49, 35.50, 35.51, 35.55, 35.57, 35.59, 35.60, 35.61, 35.63, 35.65, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.100, 35.190, 35.200, 35.204, 35.290, 35.300, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.400, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, 35.600, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.657, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047 and 35.3067 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference are 35.11(c)(1) and 35.13(2)(1).

2. Requirements in 10 Code of Federal Regulations 35 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "NRC regional office", or "director, office of nuclear material safety and safeguards" appear in 10 Code of Federal Regulations part 35, substitute the words "North Dakota department of health".

4. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

5. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations 34.

6. For references to 10 Code of Federal Regulations parts 170 and 171, see 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-08
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

Section

33-10-08-01. Purpose and scope. This chapter provides special requirements for analytical X-ray equipment. The requirements of this chapter are in addition to, and not in substitution for, applicable requirements in other chapters of this article.

History: Amended effective June 1, 1986; June 1, 1992.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

33-10-08-02. Definitions. As used in this chapter, the following definitions apply:

1. "Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.

2. "Analytical X-ray system" means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

3. "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

4. "Local components" means part of an analytical X-ray system and includes areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

5. "Normal operating procedures" means step-by-step instructions necessary to accomplish the analysis. These procedures must include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures, which are related to radiation safety.

6. "Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of the individual's body in the primary beam path during normal operation.

7. "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

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~~ chapter 33-10-04.2 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 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 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

33-10-08-04. Area requirements.

1. **Radiation levels.** The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in ~~subsection 1 of section~~ chapter 33-10-04.~~1-07~~2 . For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

2. **Surveys.**

   a. Radiation surveys, as required by ~~subsection 2 of section~~ chapter 33-10-04.~~1-07~~2, of all analytical X-ray systems sufficient to show compliance with subsection 1 of this section shall be performed:

      (1) Upon installation of the equipment, and at least once every twelve months thereafter.

      (2) Following any change in the initial arrangement, number, or type of local components in the system.

      (3) Following any maintenance requiring the disassembly or removal of a local component in the system.

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed.

(5) Any time a visual inspection of the local components in the system reveals an abnormal condition.

(6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in ~~section~~ chapter 33-10-04.~~1-06~~2.

b. Radiation survey measurements shall not be required if a registrant can demonstrate compliance with subsection 1 to the satisfaction of the department.

3. **Posting.** Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION-X-RAY EQUIPMENT", or words having a similar intent in accordance with ~~section~~ chapter 33-10-04.~~1-13~~2.

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

33-10-08-05. Operating requirements.

1. **Procedures.** Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

2. **Bypassing.** No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.

3. **Repair or modification of X-ray tube systems.** Except as specified in subsection 2 of this section, no operation involving removal of covers, shielding materials, or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe

conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

4. **Radioactive source replacement, testing, or repair.** Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

33-10-08-06. Personnel requirements.

1. **Instruction.** No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to all of the following:

   a. Identification of radiation hazards associated with the use of the equipment.

   b. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases.

   c. Proper operating procedures for the equipment.

   d. Recognition of symptoms of an acute localized exposure.

   e. Proper procedures for reporting an actual or suspected exposure.

2. **Personnel monitoring.**

   a. Finger or wrist dosimetric devices shall be provided to and shall be used by:

      (1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device.

      (2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

b. Reported dose values shall not be used for the purpose of determining compliance with ~~subsection 1 of section~~ chapter 33-10-04.~~1-06~~2 unless evaluated by a qualified expert.

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03

CHAPTER 33-10-09
RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

33-10-09-01. Purpose and scope.

1. This chapter establishes procedures for the registration and the use of particle accelerators.

2. In addition to the requirements of this chapter, all registrants are subject to the requirements of chapters 33-10-01, 33-10-02, 33-10-04.~~1~~2, and 33-10-10. Registrants engaged in industrial radiographic operations are subject to the requirements of chapter 33-10-05 and registrants engaged in the healing arts are subject to the requirements of chapter 33-10-06 or 33-10-07.~~1~~2, or both. Registrants whose operations result in the production of radioactive material are subject to the requirements of chapter 33-10-03.

History: Amended effective June 1, 1986; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-09-02. Registration procedure.

1. **Registration requirements.** No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to chapter 33-10-02.

2. **General requirements for the issuance of a registration for particle accelerators.** (Refer to chapter 33-10-02.) In addition to the requirements of chapter 33-10-02, a registration application for use of a particle accelerator will be approved only if the department determines all of the following:

   a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this chapter and chapters 33-10-

04.~~1~~2 and 33-10-10 in such a manner as to minimize danger to public health and safety or property.

b. The applicant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property.

c. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in subsection 3.

d. The applicant has appointed a radiation safety officer.

e. The applicant or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses.

f. The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the department.

g. The applicant has an adequate training program for particle accelerator operators.

3. **Human use of particle accelerators.** In addition to the requirements set forth in chapter 33-10-02, a registration for use of a particle accelerator in the healing arts will be issued only if all of the following are met:

a. Whenever deemed necessary by the department, the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation.

b. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.

c. The individual designated on the application as the user must be a physician.

History: Amended effective June 1, 1986; June 1, 1992; March 1, 1994.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-09-03. Radiation safety requirements for the use of particle accelerators.

1. **General requirements.**

   a. This section establishes radiation safety requirements for the use of particle accelerators. The requirements of this section are in addition to, and not in substitution for, other applicable requirements of the chapter.

   b. The registrant shall be responsible for assuring that all requirements of this chapter are met.

2. **Limitations.**

   a. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual has:

      (1) Been instructed in radiation safety and shall have demonstrated an understanding thereof.

      (2) Received copies of and instruction in this chapter and the applicable requirements of chapters 33-10-04.~~1~~2 and 33-10-10, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof.

      (3) Demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

   b. The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.

3. **Shielding and safety design requirements.**

   a. A qualified expert, specifically approved by the department, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

   b. Each particle accelerator installation shall be provided with such primary or secondary barriers as are necessary to assure compliance with ~~subsection 1 of section 33-10-04.1-06 and subsection 1 of section 33-10-04.1-07~~ chapter 33-10-04.2.

4. **Particle accelerator controls and interlock systems.**

a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

b. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

c. Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

d. All safety interlocks shall be designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

e. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console.

f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

5. **Warning devices.**

a. All locations designated as high radiation areas, and entrances to such locations, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

b. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for fifteen seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and all areas immediately adjacent to the high radiation areas.

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with ~~subsection 1 of section 33-10-04.1-13~~ chapter 33-10-04.2.

6. **Operating procedures.**

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the department.

d. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and maintained for inspection by the department and shall be available to the operator at each accelerator facility.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety committee or radiation safety officer.

(2) Recorded in a permanent log and a notice posted at the accelerator control console.

(3) Terminated as soon as possible.

f. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

7. **Radiation monitoring requirements.**

a. There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year, and after each servicing and repair.

b. A radiation protection survey shall be performed and documented by a qualified expert, specifically approved by the department, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

c. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

d. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

e. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

f. Whenever applicable, periodic wipe test surveys shall be made to determine the degree of contamination.

g. All surveys shall be made in accordance with the written procedures established by a qualified expert, specifically approved by the department, or the radiation safety officer of the particle accelerator facility.

h. Records of all radiation protection surveys, calibration results, instrumentation tests and wipe test results must be maintained at the accelerator facility for inspection by the department.

8. **Ventilation systems.**

a. Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in chapter 33-10-04.~~1~~2, appendix B.

b. A registrant, as required by ~~subsection 2 of section 33-10-04.1-07~~ chapter 33-10-04.2, shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in chapter 33-10-04.~~1~~2, appendix B, table II, except as authorized pursuant to ~~subsection 2 of section 33-10-04.1-14 or subdivision b of subsection 2 of section 33-10-04.1-07~~ chapter 33-10-04.2. For purposes of this subdivision, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to unrestricted areas, as far below these limits as is reasonably achievable.

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

CHAPTER 33-10-10 REPEALED

CHAPTER 33-10-10.1 ALL NEW

CHAPTER 33-10-10.1
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS - INSPECTIONS

Section
33-10-10.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 19

33-10-10.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 19. 10 Code of Federal Regulations 19.1, 19.2, 19.3, 19.5, 19.11, 19.12, 19.13, 19.14, 19.15, 19.16, 19.17, 19.18, 19.20, 19.31, and 19.32 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 19.14(a).

2. All of the requirements in chapter 33-10-10.1 apply to both licensees and registrants. A reference in 10 Code of Federal Regulations part 19 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33-10 and North Dakota Century Code chapter 23-20.1. "Registration" means the notification of the North Dakota Department of Health 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.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "administrator of the appropriate commission regional office", "administrator of the appropriate regional office", "regional office administrator", "executive director for operations", "regional administrator of the appropriate United States nuclear regulatory commission regional office" or "agency" appear in 10 Code of Federal Regulations part 19, substitute the words "North Dakota department of health".

4. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

5. State form number 8414, "notice to employees", must be

posted in place of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations 19.

6. Where 10 Code of Federal Regulations part 19 specifies contacting the United States nuclear regulatory commission, contact the North Dakota department of health.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-11
FEES FOR ISSUANCE OF LICENSE AND REGISTRATION CERTIFICATES AND INSPECTIONS

33-10-11-01. Purpose. This chapter establishes fees charged for the issuance of licenses and registration certificates by the department. This chapter also establishes fees charged to recover costs associated with nonroutine regulatory inspections and surveys of licensees and registrants.

History: Effective October 1, 1982; amended effective June 1, 1992; March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

33-10-11-02. Scope. This chapter applies to a person who is an applicant for, or a holder of, a radioactive material license or a registration certificate issued by the department.

History: Amended effective October 1, 1982
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-03, 23-20.1-04.5

33-10-11-03. Exemptions. No application fees, license fees, amendment fees, renewal fees, or special project fees, shall be required for:

1. A license authorizing the use of source material as shielding only in devices and containers; provided, however, that all other licensed byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in the device or container will be subject to the fees prescribed in appendices A and B of this chapter.

2. Nonprofit educational institutions are exempt from the fees prescribed in appendix A and B of this chapter. This exemption does not apply to those radioactive material licenses or machine

registration certificates which authorize any of the following:

a. Human use.

b. Remunerated services to other persons.

c. Distribution of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material, or products containing byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material.

d. Activities performed under a government contract.

3. The department may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of this chapter as it determines are authorized by law and are otherwise in the public interest.

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

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 new 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~~2. **Reciprocity fee.** The appropriate reciprocity fee shall accompany the written notification as required in sections 33-10-03~~-06~~.1 and 33-10-02~~-11~~.

~~5~~3. **Special project fees.** Fees for special projects are payable upon notification by the department when the review of the project is completed. Special project means 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~~4. **Annual fees.** Annual fees are required to be paid by all radioactive material licensees no later than January first of each year the license is active, except that the annual fee due on January first of the year following the issuance of a new license shall be prorated to the number of months the license was in effect the first calendar year (example: for a new license issued in May the annual fee due January first would be seven twelfths [June-December] of the annual fee listed in appendix A).

~~7~~5. **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~~6. **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 appropriate small entity fee listed in appendix A shall be paid. ~~the maximum annual fee shall be one thousand three hundred fifty dollars for industrial radiography or one thousand two hundred dollars for well logging. If the annual receipts of a small entity engaged in industrial radiography or well logging are below three hundred fifty thousand dollars, the annual fee is five hundred dollars.~~

a. A licensee qualifies as a small entity if it meets the following size standards:

(1) A small business is a business with annual receipts of three and one-half million dollars or less.

(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' 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~~7. **Method of payment.** Fee payments shall be by check, draft, or money order made payable to the North Dakota department of health. Payment may also be made by credit card by calling 701-328-5188.

~~10~~8. **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 Department of Health
Division of Air Quality
~~1200 Missouri Avenue, Room 304~~
~~Box 5520~~
918 E Divide Avenue, 2nd Floor
Bismarck, ND ~~58506-5520~~ 58501-1947

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

33-10-11-05. Failure by applicant or licensee to pay prescribed fees.

1. In any case where the department finds that an applicant or a licensee has failed to pay a prescribed fee required in this chapter, the department will not process any application and may suspend or revoke any license or approval involved or may issue an order with respect to licensed activities as the department determines to be appropriate or necessary in order to carry out the provisions of this chapter and of the North Dakota Century Code.

2. In any case where the department does not receive the prescribed fee by the stated due date, an additional fee shall be levied as stated in category ~~30~~ 27 of appendix A.

History: Effective October 1, 1982; March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-04, 23-20.1-04.5

Appendix A - Schedule of Fees for 2010 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the ~~following~~ fees listed in the radioactive material program's fees web page (_____). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase annually. Thereafter, the fees will be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next years fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Non-routine inspection Annual Fee	Full cost $96,880	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Non-routine inspection Annual Fee	N/A N/A	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$590 $830	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Non-routine inspection Annual Fee	$590 $1,240	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Non-routine inspection Annual Fee	Full cost $503,740	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only.	Non-routine inspection Annual Fee	$180 $300	Items 23 and/or 27 as applicable
C	All other source material licenses.	Non-routine inspection Annual Fee	$670 $2,070	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,420 $5,900	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$890 $2,710	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$850 $5,900	Items 23 and/or 27 as applicable
D	License and approvals issued pursuant to chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material.	Non-routine inspection Annual Fee	$530 $2,360	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
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).	Non-routine inspection Annual Fee	$310 $1,060	Items 23 and/or 27 as applicable
F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$350 $1,030	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$620 $9,440	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33-10-03.	Non-routine inspection Annual Fee	$470 $3,070	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33-10-03	Non-routine inspection Annual Fee	$310 $4,250	Items 23 and/or 27 as applicable
K	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Non-routine inspection Annual Fee	$460 $1,180	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$530 $1,770	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$410 $1,650	Items 23 and/or 27 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Non-routine inspection Annual Fee	$460 $2,670	Items 23 and/or 27 as applicable
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-05 for industrial radiographic operations.	Non-routine inspection Annual Fee Annual Fee (Samll Entity)	$1,110 $3,600 $1,590	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Categories 4A through 10D.	Non-routine inspection Annual Fee	$800 $1,030	Items 23 and/or 27 as applicable
1	Portable x-ray fluorescence analyzers only.	Non-routine inspection Annual Fee	$410 $590	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
Q	Registration of a device(s) generally licensed under Chapter 33-10-03.	Non-routine inspection	$300	Items 23 and/or 27 as applicable
		Annual Fee	$590	
	(Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)			
4. WASTE DISPOSAL AND PROCESSING				
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$58,880	
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$930	Items 23 and/or 27 as applicable
		Annual Fee	$7,080	
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$930	Items 23 and/or 27 as applicable
		Annual Fee	$3,300	
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	Non-routine inspection	$530	Items 23 and/or 27 as applicable
		Annual Fee	$2,950	
		Annual Fee (Small Entity)	$1,420	
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$6,840	
		Annual Fee (Small Entity)	$4,720	
6. NUCLEAR LAUNDRY				
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.	Non-routine inspection	$850	Items 23 and/or 27 as applicable
		Annual Fee	$3,190	
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURIN 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.	Non-routine inspection	$850	Items 23 and/or 27 as applicable
		Annual Fee	$7,320	
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.	Non-routine inspection	$800	Items 23 and/or 27 as applicable
		Annual Fee	$7,670	
			$0	
C	Other licenses issued pursuant to chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Non-routine inspection	$670	Items 23 and/or 27 as applicable
		Annual Fee	$2,600	

Category	Description	Base Fees (USD)		Additional Charges
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Non-routine inspection Annual Fee	$530 $1,530	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Non-routine inspection Annual Fee	$530 $1,770	Items 23 and/or 27 as applicable
9.	Civil Defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Non-routine inspection Annual Fee	$310 $830	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	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.	Non-routine inspection Annual Fee	$310 $830	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. Import and Export Licenses (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03.	Annual Fee	Same as Annual Fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due 3 working days prior to entering the State)	Non-routine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Non-routine inspection Annual Fee	$410 $770	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$410 $770	Items 23 and/or 27 as applicable
16.	Combination Leak test and analysis services and instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$470 $1,030	Items 23 and/or 27 as applicable
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Non-routine inspection Annual Fee	$300 $530	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only.	Non-routine inspection Annual Fee	$410 $710	Items 23 and/or 27 as applicable
19	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Non-routine inspection Annual Fee	$590 $9,440	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$240	Item 27 as applicable.
21.	Demonstration and sales of devices containing radioactive materials.	Annual Fee	$240	Item 27 as applicable.
22.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$900	Item 27 as applicable.

Category	Description	Base Fees (USD)		Additional Charges
23.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6, or 21 above.)	Annual Fee	25% of Base Fee for Category Type Per Location	Item 27 as applicable.
24.	Administrative amendment (limited to the following amendments only): - Cororate name chage with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manual changes (industral users only) - Filing training cetrtificates (guages users only)	Ammendment	$120	Item 27 as applicable.
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full cost	Item 27 as applicable.
26.	Certificate - in vitro testing with radioactive material under general license.	Certificate (Valid for 3 years)	$140	Item 27 as applicable.
27.	Late payment of any fees described in items 1-27 above.	From payment due date	$1	An additional fee per day after 30 days late.

Appendix A - Schedule of Fees for 2011 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the ~~following~~ fees listed in the radioactive material program's fees web page (_____). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase annually. Thereafter, the fees will be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next years fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Non-routine inspection Annual Fee	Full cost $114,320	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Non-routine inspection Annual Fee	N/A N/A	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$700 $980	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Non-routine inspection Annual Fee	$700 $1,460	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Non-routine inspection Annual Fee	Full cost $594,410	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only.	Non-routine inspection Annual Fee	$210 $350	Items 23 and/or 27 as applicable
C	All other source material licenses.	Non-routine inspection Annual Fee	$790 $2,440	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,680 $6,960	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,050 $3,200	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,000 $6,960	Items 23 and/or 27 as applicable
D	License and approvals issued pursuant to chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material.	Non-routine inspection Annual Fee	$630 $2,780	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
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).	Non-routine inspection Annual Fee	$370 $1,250	Items 23 and/or 27 as applicable
F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$410 $1,220	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$730 $11,140	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33-10-03.	Non-routine inspection Annual Fee	$550 $3,620	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33-10-03	Non-routine inspection Annual Fee	$370 $5,020	Items 23 and/or 27 as applicable
K	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Non-routine inspection Annual Fee	$540 $1,390	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$630 $2,090	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$480 $1,950	Items 23 and/or 27 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Non-routine inspection Annual Fee	$540 $3,150	Items 23 and/or 27 as applicable
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-05 for industrial radiographic operations.	Non-routine inspection Annual Fee Annual Fee (Samll Entity)	$1,310 $4,250 $1,880	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Categories 4A through 10D.	Non-routine inspection Annual Fee	$940 $1,220	Items 23 and/or 27 as applicable
1	Portable x-ray fluorescence analyzers only.	Non-routine inspection Annual Fee	$480 $700	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
Q	Registration of a device(s) generally licensed under Chapter 33-10-03. (Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)	Non-routine inspection Annual Fee	$350 $700	Items 23 and/or 27 as applicable
4. WASTE DISPOSAL AND PROCESSING				
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection Annual Fee	Full cost $69,480	Items 23 and/or 27 as applicable
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection Annual Fee	$1,100 $8,350	Items 23 and/or 27 as applicable
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection Annual Fee	$1,100 $3,890	Items 23 and/or 27 as applicable
5. WELL LOGGING				
A	Licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies	Non-routine inspection Annual Fee Annual Fee (Small Entity)	$630 $3,480 $1,680	Items 23 and/or 27 as applicable
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Non-routine inspection Annual Fee Annual Fee (Small Entity)	Full cost $8,070 $5,570	Items 23 and/or 27 as applicable
6. NUCLEAR LAUNDRY				
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.	Non-routine inspection Annual Fee	$1,000 $3,760	Items 23 and/or 27 as applicable
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURIN 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.	Non-routine inspection Annual Fee	$1,000 $8,640	Items 23 and/or 27 as applicable
B	Licenses of broad scope issued to medical institutions or two or more physicians pursuant to chapter 33-10-03 authorizing research and development, including human use of byproduct material, except licenses for byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in sealed sources contained in teletherapy devices.	Non-routine inspection Annual Fee	$940 $9,050 $0	Items 23 and/or 27 as applicable
C	Other licenses issued pursuant to chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Non-routine inspection Annual Fee	$790 $3,070	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Non-routine inspection Annual Fee	$630 $1,810	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Non-routine inspection Annual Fee	$630 $2,090	Items 23 and/or 27 as applicable
9.	Civil Defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Non-routine inspection Annual Fee	$370 $980	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	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.	Non-routine inspection Annual Fee	$370 $980	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. Import and Export Licenses (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03.	Annual Fee	Same as Annual Fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due 3 working days prior to entering the State)	Non-routine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Non-routine inspection Annual Fee	$480 $910	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$480 $910	Items 23 and/or 27 as applicable
16.	Combination Leak test and analysis services and instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$550 $1,220	Items 23 and/or 27 as applicable
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Non-routine inspection Annual Fee	$350 $630	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only.	Non-routine inspection Annual Fee	$480 $840	Items 23 and/or 27 as applicable
19	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Non-routine inspection Annual Fee	$700 $11,140	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$280	Item 27 as applicable.
21.	Demonstration and sales of devices containing radioactive materials.	Annual Fee	$280	Item 27 as applicable.
22.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$1,060	Item 27 as applicable.

Category	Description	Base Fees (USD)		Additional Charges
23.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6, or 21 above.)	Annual Fee	25% of Base Fee for Category Type Per Location	Item 27 as applicable.
24.	Administrative amendment (limited to the following amendments only): - Cororate name chage with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manula changes (industral users only) - Filing training cetrtificates (guages users only)	Ammendment	$140	Item 27 as applicable.
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full cost	Item 27 as applicable.
26.	Certificate - in vitro testing with radioactive material under general license.	Certificate (Valid for 3 years)	$170	Item 27 as applicable.
27.	Late payment of any fees described in items 1-27 above.	From payment due date	$1	An additional fee per day after 30 days late.

Appendix A - Schedule of Fees for 2012 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the ~~following~~ fees listed in the radioactive material program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase annually. Thereafter, the fees will be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next years fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Non-routine inspection Annual Fee	Full cost $134,900	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Non-routine inspection Annual Fee	N/A N/A	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$830 $1,160	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Non-routine inspection Annual Fee	$830 $1,720	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Non-routine inspection Annual Fee	Full cost $701,400	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only.	Non-routine inspection Annual Fee	$250 $410	Items 23 and/or 27 as applicable
C	All other source material licenses.	Non-routine inspection Annual Fee	$930 $2,880	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,980 $8,210	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,240 $3,780	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,180 $8,210	Items 23 and/or 27 as applicable
D	License and approvals issued pursuant to chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material.	Non-routine inspection Annual Fee	$740 $3,280	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
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).	Non-routine inspection Annual Fee	$440 $1,480	Items 23 and/or 27 as applicable
F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$480 $1,440	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$860 $13,150	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33-10-03.	Non-routine inspection Annual Fee	$650 $4,270	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33-10-03	Non-routine inspection Annual Fee	$440 $5,920	Items 23 and/or 27 as applicable
K	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Non-routine inspection Annual Fee	$640 $1,640	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$740 $2,470	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$570 $2,300	Items 23 and/or 27 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Non-routine inspection Annual Fee	$640 $3,720	Items 23 and/or 27 as applicable
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-05 for industrial radiographic operations.	Non-routine inspection Annual Fee Annual Fee (Samll Entity)	$1,550 $5,020 $2,220	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Categories 4A through 10D.	Non-routine inspection Annual Fee	$1,110 $1,440	Items 23 and/or 27 as applicable
1	Portable x-ray fluorescence analyzers only.	Non-routine inspection Annual Fee	$570 $830	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
Q	Registration of a device(s) generally licensed under Chapter 33-10-03.	Non-routine inspection	$410	Items 23 and/or 27 as applicable
		Annual Fee	$830	
	(Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)			
4. WASTE DISPOSAL AND PROCESSING				
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$81,990	
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$1,300	Items 23 and/or 27 as applicable
		Annual Fee	$9,850	
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$1,300	Items 23 and/or 27 as applicable
		Annual Fee	$4,590	
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	Non-routine inspection	$740	Items 23 and/or 27 as applicable
		Annual Fee	$4,110	
		Annual Fee (Small Entity)	$1,980	
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$9,520	
		Annual Fee (Small Entity)	$6,570	
6. NUCLEAR LAUNDRY				
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.	Non-routine inspection	$1,180	Items 23 and/or 27 as applicable
		Annual Fee	$4,440	
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURIN 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.	Non-routine inspection	$1,180	Items 23 and/or 27 as applicable
		Annual Fee	$10,200	
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.	Non-routine inspection	$1,110	Items 23 and/or 27 as applicable
		Annual Fee	$10,680	
			$0	
C	Other licenses issued pursuant to chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Non-routine inspection	$930	Items 23 and/or 27 as applicable
		Annual Fee	$3,620	

Category	Description	Base Fees (USD)		Additional Charges
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Non-routine inspection Annual Fee	$740 $2,140	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Non-routine inspection Annual Fee	$740 $2,470	Items 23 and/or 27 as applicable
9.	Civil Defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Non-routine inspection Annual Fee	$440 $1,160	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	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.	Non-routine inspection Annual Fee	$440 $1,160	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. Import and Export Licenses (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03.	Annual Fee	Same as Annual Fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due 3 working days prior to entering the State)	Non-routine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Non-routine inspection Annual Fee	$570 $1,070	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$570 $1,070	Items 23 and/or 27 as applicable
16.	Combination Leak test and analysis services and instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$650 $1,440	Items 23 and/or 27 as applicable
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Non-routine inspection Annual Fee	$410 $740	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only.	Non-routine inspection Annual Fee	$570 $990	Items 23 and/or 27 as applicable
19	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Non-routine inspection Annual Fee	$830 $13,150	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$330	Item 27 as applicable.
21.	Demonstration and sales of devices containing radioactive materials.	Annual Fee	$330	Item 27 as applicable.
22.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$1,250	Item 27 as applicable.

Category	Description	Base Fees (USD)		Additional Charges
23.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6, or 21 above.)	Annual Fee	25% of Base Fee for Category Type Per Location	Item 27 as applicable.
24.	Administrative amendment (limited to the following amendments only): - Cororate name chage with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manula changes (industral users only) - Filing training cetrtificates (guages users only)	Ammendment	$170	Item 27 as applicable.
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full cost	Item 27 as applicable.
26.	Certificate - in vitro testing with radioactive material under general license.	Certificate (Valid for 3 years)	$200	Item 27 as applicable.
27.	Late payment of any fees described in items 1-27 above.	From payment due date	$1	An additional fee per day after 30 days late.

Appendix A - Schedule of Fees for 2013 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the ~~following~~ fees listed in the radioactive material program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase annually. Thereafter, the fees will be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next years fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Non-routine inspection Annual Fee	Full cost $159,180	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Non-routine inspection Annual Fee	N/A N/A	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$980 $1,370	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Non-routine inspection Annual Fee	$980 $2,030	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Non-routine inspection Annual Fee	Full cost $827,650	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only.	Non-routine inspection Annual Fee	$300 $480	Items 23 and/or 27 as applicable
C	All other source material licenses.	Non-routine inspection Annual Fee	$1,100 $3,400	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$2,340 $9,690	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,460 $4,460	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,390 $9,690	Items 23 and/or 27 as applicable
D	License and approvals issued pursuant to chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material.	Non-routine inspection Annual Fee	$870 $3,870	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
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).	Non-routine inspection Annual Fee	$520 $1,750	Items 23 and/or 27 as applicable
F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$570 $1,700	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$1,010 $15,520	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33-10-03.	Non-routine inspection Annual Fee	$770 $5,040	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33-10-03.	Non-routine inspection Annual Fee	$520 $6,990	Items 23 and/or 27 as applicable
K	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Non-routine inspection Annual Fee	$760 $1,940	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$870 $2,910	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$670 $2,710	Items 23 and/or 27 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Non-routine inspection Annual Fee	$760 $4,390	Items 23 and/or 27 as applicable
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-05 for industrial radiographic operations.	Non-routine inspection Annual Fee Annual Fee (Samll Entity)	$1,830 $5,920 $2,620	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Categories 4A through 10D.	Non-routine inspection Annual Fee	$1,310 $1,700	Items 23 and/or 27 as applicable
1	Portable x-ray fluorescence analyzers only.	Non-routine inspection Annual Fee	$670 $980	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
Q	Registration of a device(s) generally licensed under Chapter 33-10-03.	Non-routine inspection	$480	Items 23 and/or 27 as applicable
		Annual Fee	$980	
	(Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)			
4. WASTE DISPOSAL AND PROCESSING				
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$96,750	
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$1,530	Items 23 and/or 27 as applicable
		Annual Fee	$11,620	
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$1,530	Items 23 and/or 27 as applicable
		Annual Fee	$5,420	
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	Non-routine inspection	$870	Items 23 and/or 27 as applicable
		Annual Fee	$4,850	
		Annual Fee (Small Entity)	$2,340	
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$11,230	
		Annual Fee (Small Entity)	$7,750	
6. NUCLEAR LAUNDRY				
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.	Non-routine inspection	$1,390	Items 23 and/or 27 as applicable
		Annual Fee	$5,240	
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURIN 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.	Non-routine inspection	$1,390	Items 23 and/or 27 as applicable
		Annual Fee	$12,040	
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.	Non-routine inspection	$1,310	Items 23 and/or 27 as applicable
		Annual Fee	$12,600	
			$0	
C	Other licenses issued pursuant to chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Non-routine inspection	$1,100	Items 23 and/or 27 as applicable
		Annual Fee	$4,270	

Category	Description	Base Fees (USD)		Additional Charges
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Non-routine inspection Annual Fee	$870 $2,530	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Non-routine inspection Annual Fee	$870 $2,910	Items 23 and/or 27 as applicable
9.	Civil Defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Non-routine inspection Annual Fee	$520 $1,370	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	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.	Non-routine inspection Annual Fee	$520 $1,370	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. Import and Export Licenses (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03.	Annual Fee	Same as Annual Fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due 3 working days prior to entering the State)	Non-routine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Non-routine inspection Annual Fee	$670 $1,260	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$670 $1,260	Items 23 and/or 27 as applicable
16.	Combination Leak test and analysis services and instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$770 $1,700	Items 23 and/or 27 as applicable
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Non-routine inspection Annual Fee	$480 $870	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only.	Non-routine inspection Annual Fee	$670 $1,170	Items 23 and/or 27 as applicable
19	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Non-routine inspection Annual Fee	$980 $15,520	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$390	Item 27 as applicable.
21.	Demonstration and sales of devices containing radioactive materials.	Annual Fee	$390	Item 27 as applicable.
22.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$1,480	Item 27 as applicable.

Category	Description	Base Fees (USD)		Additional Charges
23.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6, or 21 above.)	Annual Fee	25% of Base Fee for Category Type Per Location	Item 27 as applicable.
24.	Administrative amendment (limited to the following amendments only): - Cororate name chage with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manula changes (industral users only) - Filing training cetrtificates (guages users only)	Ammendment	$200	Item 27 as applicable.
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full cost	Item 27 as applicable.
26.	Certificate - in vitro testing with radioactive material under general license.	Certificate (Valid for 3 years)	$240	Item 27 as applicable.
27.	Late payment of any fees described in items 1-27 above.	From payment due date	$1	An additional fee per day after 30 days late.

Appendix A - Schedule of Fees for 2014 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the ~~following~~ fees listed in the radioactive material program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase annually. Thereafter, the fees will be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next years fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Non-routine inspection Annual Fee	Full cost $187,830	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Non-routine inspection Annual Fee	N/A N/A	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,160 $1,620	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Non-routine inspection Annual Fee	$1,160 $2,400	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Non-routine inspection Annual Fee	Full cost $976,630	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only.	Non-routine inspection Annual Fee	$350 $570	Items 23 and/or 27 as applicable
C	All other source material licenses.	Non-routine inspection Annual Fee	$1,300 $4,010	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$2,760 $11,430	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$1,720 $5,260	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,640 $11,430	Items 23 and/or 27 as applicable
D	License and approvals issued pursuant to chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material.	Non-routine inspection Annual Fee	$1,030 $4,570	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
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).	Non-routine inspection Annual Fee	$610 $2,070	Items 23 and/or 27 as applicable
F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$670 $2,010	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$1,190 $18,310	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33-10-03.	Non-routine inspection Annual Fee	$910 $5,950	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33-10-03	Non-routine inspection Annual Fee	$610 $8,250	Items 23 and/or 27 as applicable
K	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Non-routine inspection Annual Fee	$900 $2,290	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$1,030 $3,430	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$790 $3,200	Items 23 and/or 27 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Non-routine inspection Annual Fee	$900 $5,180	Items 23 and/or 27 as applicable
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-05 for industrial radiographic operations.	Non-routine inspection Annual Fee Annual Fee (Samll Entity)	$2,160 $6,990 $3,090	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Categories 4A through 10D.	Non-routine inspection Annual Fee	$1,550 $2,010	Items 23 and/or 27 as applicable
1	Portable x-ray fluorescence analyzers only.	Non-routine inspection Annual Fee	$790 $1,160	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
Q	Registration of a device(s) generally licensed under Chapter 33-10-03. (Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)	Non-routine inspection Annual Fee	$570 $1,160	Items 23 and/or 27 as applicable
4. WASTE DISPOSAL AND PROCESSING				
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection Annual Fee	Full cost $114,170	Items 23 and/or 27 as applicable
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection Annual Fee	$1,810 $13,710	Items 23 and/or 27 as applicable
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection Annual Fee	$1,810 $6,400	Items 23 and/or 27 as applicable
5. WELL LOGGING				
A	Licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies	Non-routine inspection Annual Fee Annual Fee (Small Entity)	$1,030 $5,720 $2,760	Items 23 and/or 27 as applicable
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Non-routine inspection Annual Fee Annual Fee (Small Entity)	Full cost $13,250 $9,150	Items 23 and/or 27 as applicable
6. NUCLEAR LAUNDRY				
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.	Non-routine inspection Annual Fee	$1,640 $6,180	Items 23 and/or 27 as applicable
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURIN 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.	Non-routine inspection Annual Fee	$1,640 $14,210	Items 23 and/or 27 as applicable
B	Licenses of broad scope issued to medical institutions or two or more physicians pursuant to chapter 33-10-03 authorizing research and development, including human use of byproduct material, except licenses for byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in sealed sources contained in teletherapy devices.	Non-routine inspection Annual Fee	$1,550 $14,870 $0	Items 23 and/or 27 as applicable
C	Other licenses issued pursuant to chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Non-routine inspection Annual Fee	$1,300 $5,040	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Non-routine inspection Annual Fee	$1,030 $2,990	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Non-routine inspection Annual Fee	$1,030 $3,430	Items 23 and/or 27 as applicable
9.	Civil Defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Non-routine inspection Annual Fee	$610 $1,620	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	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.	Non-routine inspection Annual Fee	$610 $1,620	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. Import and Export Licenses (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03.	Annual Fee	Same as Annual Fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due 3 working days prior to entering the State)	Non-routine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Non-routine inspection Annual Fee	$790 $1,490	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$790 $1,490	Items 23 and/or 27 as applicable
16.	Combination Leak test and analysis services and instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$910 $2,010	Items 23 and/or 27 as applicable
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Non-routine inspection Annual Fee	$570 $1,030	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only.	Non-routine inspection Annual Fee	$790 $1,380	Items 23 and/or 27 as applicable
19	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Non-routine inspection Annual Fee	$1,160 $18,310	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$460	Item 27 as applicable.
21.	Demonstration and sales of devices containing radioactive materials.	Annual Fee	$460	Item 27 as applicable.
22.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$1,750	Item 27 as applicable.

Category	Description	Base Fees (USD)		Additional Charges
23.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6, or 21 above.)	Annual Fee	25% of Base Fee for Category Type Per Location	Item 27 as applicable.
24.	Administrative amendment (limited to the following amendments only): - Cororate name chage with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manula changes (industral users only) - Filing training cetrtificates (guages users only)	Ammendment	$240	Item 27 as applicable.
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full cost	Item 27 as applicable.
26.	Certificate - in vitro testing with radioactive material under general license.	Certificate (Valid for 3 years)	$280	Item 27 as applicable.
27.	Late payment of any fees described in items 1-27 above.	From payment due date	$1	An additional fee per day after 30 days late.

Appendix A - Schedule of Fees for 2015 Radioactive Material Licenses

Applicants for radioactive material licenses and other regulatory services and holders of radioactive material licenses shall pay the ~~following~~ fees listed in the radioactive material program's fees web page (_____). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase annually. Thereafter, the fees will be adjusted on an annual basis to account for any increase in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next years fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Category	Description	Base Fees (USD)		Additional Charges
1. SPECIAL NUCLEAR MATERIAL				
A	Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.	Non-routine inspection Annual Fee	Full cost $221,640	Items 23 and/or 27 as applicable
B	Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation. (Regulated by NRC)	Non-routine inspection Annual Fee	N/A N/A	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,370 $1,910	Items 23 and/or 27 as applicable
D	All other special nuclear material licenses except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity.	Non-routine inspection Annual Fee	$1,370 $2,830	Items 23 and/or 27 as applicable
2. SOURCE MATERIAL				
A	Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, or buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Non-routine inspection Annual Fee	Full cost $1,152,420	Items 23 and/or 27 as applicable
B	Licenses for possession, use and or installation of source material for shielding only.	Non-routine inspection Annual Fee	$410 $670	Items 23 and/or 27 as applicable
C	All other source material licenses.	Non-routine inspection Annual Fee	$1,530 $4,730	Items 23 and/or 27 as applicable
3. BYPRODUCT, NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL				
A	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$3,260 $13,490	Items 23 and/or 27 as applicable
B	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for processing or manufacturing of items containing byproduct material or naturally occurring or accelerator-produced radioactive material for commercial distribution.	Non-routine inspection Annual Fee	$2,030 $6,210	Items 23 and/or 27 as applicable
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.	Non-routine inspection Annual Fee	$1,940 $13,490	Items 23 and/or 27 as applicable
D	License and approvals issued pursuant to chapter 33-10-03 authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material or naturally occurring or accelerator-produced radioactive material.	Non-routine inspection Annual Fee	$1,220 $5,390	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
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).	Non-routine inspection Annual Fee	$720 $2,440	Items 23 and/or 27 as applicable
F	License for possession and use of less than 370 terabecquerels [10,000 curies] of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$790 $2,370	Items 23 and/or 27 as applicable
G	Licenses for possession and use of 370 terabecquerels [10,000 curies] or more of byproduct material or naturally occurring or accelerator-produced radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	Non-routine inspection Annual Fee	$1,400 $21,610	Items 23 and/or 27 as applicable
H	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material that require device review to persons exempt from the licensing requirements of chapter 33-10-03, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licenses of chapter 33-10-03.	Non-routine inspection Annual Fee	$1,070 $7,020	Items 23 and/or 27 as applicable
I	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require device evaluation to persons exempt from the licensing requirements of chapter 33-10-03, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of chapter 33-10-03	Non-routine inspection Annual Fee	$720 $9,740	Items 23 and/or 27 as applicable
K	Licenses issued pursuant to chapter 33-10-03 to distribute items containing byproduct material or naturally occurring or accelerator-produced radioactive material, or quantities of byproduct material or naturally occurring or accelerator-produced radioactive material that do not require sealed source and/or device review to persons generally licensed under this chapter, except specific licenses authorizing for redistribution of items that have been authorized for distribution to persons generally licensed under this chapter.	Non-routine inspection Annual Fee	$1,060 $2,700	Items 23 and/or 27 as applicable
L	Licenses of broad scope for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$1,220 $4,050	Items 23 and/or 27 as applicable
M	Other licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-03 for research and development that do not authorize commercial distribution.	Non-routine inspection Annual Fee	$930 $3,780	Items 23 and/or 27 as applicable
N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration or leak testing services only are subject to the fees specified in fee Categories 18 and 19, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	Non-routine inspection Annual Fee	$1,060 $6,110	Items 23 and/or 27 as applicable
O	License for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material issued pursuant to chapter 33-10-05 for industrial radiographic operations.	Non-routine inspection Annual Fee Annual Fee (Samll Entity)	$2,550 $8,250 $3,650	Items 23 and/or 27 as applicable
P	All other specific byproduct material or naturally occurring or accelerator-produced radioactive material licenses, except as described in items 1-6 below or listed in Categories 4A through 10D.	Non-routine inspection Annual Fee	$1,830 $2,370	Items 23 and/or 27 as applicable
1	Portable x-ray fluorescence analyzers only.	Non-routine inspection Annual Fee	$930 $1,370	Items 23 and/or 27 as applicable

Category	Description	Base Fees (USD)		Additional Charges
Q	Registration of a device(s) generally licensed under Chapter 33-10-03.	Non-routine inspection	$670	Items 23 and/or 27 as applicable
		Annual Fee	$1,370	
	(Each address or location where the device(s) are used or stored represents a separate general license and requires a separate registration and fee.)			
4. WASTE DISPOSAL AND PROCESSING				
A	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$134,720	
B	Licenses specifically authorizing the receipt of waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$2,140	Items 23 and/or 27 as applicable
		Annual Fee	$16,180	
C	Licenses specifically authorizing the receipt of prepackaged waste byproduct material, naturally occurring, technologically enhanced, 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.	Non-routine inspection	$2,140	Items 23 and/or 27 as applicable
		Annual Fee	$7,550	
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	Non-routine inspection	$1,220	Items 23 and/or 27 as applicable
		Annual Fee	$6,750	
		Annual Fee (Small Entity)	$3,260	
B	Licenses for possession and use of byproduct material or naturally occurring or accelerator-produced radioactive material, for field flooding tracer studies.	Non-routine inspection	Full cost	Items 23 and/or 27 as applicable
		Annual Fee	$15,640	
		Annual Fee (Small Entity)	$10,800	
6. NUCLEAR LAUNDRY				
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.	Non-routine inspection	$1,940	Items 23 and/or 27 as applicable
		Annual Fee	$7,290	
7. HUMAN USE OF BYPRODUCT, NATURALLY OCCURIN 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.	Non-routine inspection	$1,940	Items 23 and/or 27 as applicable
		Annual Fee	$16,770	
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.	Non-routine inspection	$1,830	Items 23 and/or 27 as applicable
		Annual Fee	$17,550	
			$0	
C	Other licenses issued pursuant to chapter 33-10-03 for human use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, and/or special nuclear material, except licenses for byproduct material, source material, naturally occurring or accelerator-produced radioactive material, special nuclear material in sealed sources contained in teletherapy devices, or as listed in items 1-4 below.	Non-routine inspection	$1,530	Items 23 and/or 27 as applicable
		Annual Fee	$5,950	

Category	Description	Base Fees (USD)		Additional Charges
8. VETERINARY MEDICINE				
A	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic procedures only.	Non-routine inspection Annual Fee	$1,220 $3,530	Items 23 and/or 27 as applicable
B	Licenses issued for the veterinary use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material in animals for diagnostic and/or therapeutic procedures.	Non-routine inspection Annual Fee	$1,220 $4,050	Items 23 and/or 27 as applicable
9.	Civil Defense licenses for possession and use of byproduct material, naturally occurring or accelerator-produced radioactive material, source material, or special nuclear material for civil defense activities.	Non-routine inspection Annual Fee	$720 $1,910	Items 23 and/or 27 as applicable
10. DEVICE, PRODUCT OR SEALED SOURCE SAFETY EVALUATION (Regulated by NRC)				
11.	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.	Non-routine inspection Annual Fee	$720 $1,910	Items 23 and/or 27 as applicable
12. SPENT FUEL STORAGE (Regulated by NRC)				
13. Import and Export Licenses (Regulated by NRC)				
14.	Reciprocity: Other agreement state and/or NRC licensees who conduct activities in North Dakota under the reciprocity provisions of chapters 33-10-02 and 33-10-03.	Annual Fee	Same as Annual Fee for license type	Items 23 and/or 27 as applicable
	(Application fee is due 3 working days prior to entering the State)	Non-routine inspection	Same as inspection fee for license type	
15. SERVICES FOR OTHER LICENSED ENTITIES				
A	Leak test and analysis services (for other licensed entities) only.	Non-routine inspection Annual Fee	$930 $1,760	Items 23 and/or 27 as applicable
B	Instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$930 $1,760	Items 23 and/or 27 as applicable
16.	Combination Leak test and analysis services and instrument calibration services (for other licensed entities) only.	Non-routine inspection Annual Fee	$1,070 $2,370	Items 23 and/or 27 as applicable
17.	Calibration and/or reference sources (not for providing service to other licensed entities) only.	Non-routine inspection Annual Fee	$670 $1,220	Items 23 and/or 27 as applicable
18.	Storage of radioactive material only.	Non-routine inspection Annual Fee	$930 $1,630	Items 23 and/or 27 as applicable
19	Providing deliberate operations to reduce or remove residual radioactivity from equipment, facilities, and land owned, possessed, or controlled by other persons to a level that permits release of equipment, facilities, and land for unrestricted use and/or termination of a license rendered from a fixed facility or a mobile unit.	Non-routine inspection Annual Fee	$1,370 $21,610	Items 23 and/or 27 as applicable
20.	Radiation training courses involving the use of licensed material by the instructor and/or the participants.	Annual Fee	$540	Item 27 as applicable.
21.	Demonstration and sales of devices containing radioactive materials.	Annual Fee	$540	Item 27 as applicable.
22.	Installation, removal, repair and servicing of devices containing radioactive materials.	Annual Fee	$2,070	Item 27 as applicable.

Category	Description	Base Fees (USD)		Additional Charges
23.	Multiple offices: Add the following fees per additional office location. (This category does not apply to additional licensed locations in Categories 3.P.3 to 3.P.6, or 21 above.)	Annual Fee	25% of Base Fee for Category Type Per Location	Item 27 as applicable.
24.	Administrative amendment (limited to the following amendments only): - Cororate name chage with no radiation safety program changes - Change of mailing address only (no change to locations of use) - Minor O&E procedures manula changes (industral users only) - Filing training cetrtificates (guages users only)	Ammendment	$280	Item 27 as applicable.
25.	Inspection of radioactive materials package shipments to low-level radioactive waste disposal facility.	Inspection	Full cost	Item 27 as applicable.
26.	Certificate - in vitro testing with radioactive material under general license.	Certificate (Valid for 3 years)	$330	Item 27 as applicable.
27.	Late payment of any fees described in items 1-27 above.	From payment due date	$1	An additional fee per day after 30 days late.

Appendix B
2010 Schedule Of Fees For Registration
Certification And Inspecton

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed in the x-ray program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase. Thereafter, the fees will be adjusted on an annual basis to account for any change in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next year's fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	$110
Medical:	
A. Radiographic machine (including computer tomography)	$170
B. Fluoroscopic Machine	$260
C. Combined Radiographic-Fluoroscopic	$350
D. (1) Therapeutic: Linear Accelerator (Less that 10MEV)	$260
(2) Therapeutic: Linear Accelerator (Greater thatn 10MEV)	$430
E. Superficial X-ray	$130
Chiropractic	$160
Podiatry	$130
Veterinary Medicine	$110
Industrial Radiography	$430
Accelerators (Industrial and Research)	$260
Education and Research	$260

Other Registration Fees and Services	Annual Service Fees (In U.S. dollars)
X-ray Services and Installers	$260
Radiation T Training Courses	$170
X-ray Sales and Demonstrations	$260
combined Sales and Service (Assembler)	$350
Dosimeterists and Physicists	$170
Shielding Evaluations (Routine)	$260 Per Evaluation
Shielding Evaluations (Nonroutine)	Full Cost
Reciprocity (X-ray producing Machines)	$260 Per Year Per Machine

Appendix B
2011 Schedule Of Fees For Registration
Certification And Inspecton

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed in the x-ray program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase. Thereafter, the fees will be adjusted on an annual basis to account for any change in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next year's fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	$130
Medical:	
A. Radiographic machine (including computer tomography)	$200
B. Fluoroscopic Machine	$300
C. Combined Radiographic-Fluoroscopic	$400
D. (1) Therapeutic: Linear Accelerator (Less that 10MEV)	$300
(2) Therapeutic: Linear Accelerator (Greater thatn 10MEV)	$490
E. Superficial X-ray	$150
Chiropractic	$180
Podiatry	$150
Veterinary Medicine	$130
Industrial Radiography	$490
Accelerators (Industrial and Research)	$300
Education and Research	$300

Other Registration Fees and Services	Annual Service Fees (In U.S. dollars)
X-ray Services and Installers	$300
Radiation T Training Courses	$200
X-ray Sales and Demonstrations	$300
combined Sales and Service (Assembler)	$400
Dosimeterists and Physicists	$200
Shielding Evaluations (Routine)	$300 Per Evaluation
Shielding Evaluations (Nonroutine)	Full Cost
Reciprocity (X-ray producing Machines)	$300 Per Year Per Machine

Appendix B
2012 Schedule Of Fees For Registration
Certification And Inspecton

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed in the x-ray program's fees web page (_____). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase. Thereafter, the fees will be adjusted on an annual basis to account for any change in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next year's fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	$150
Medical:	
A. Radiographic machine (including computer tomography)	$230
B. Fluoroscopic Machine	$350
C. Combined Radiographic-Fluoroscopic	$460
D. (1) Therapeutic: Linear Accelerator (Less that 10MEV)	$350
(2) Therapeutic: Linear Accelerator (Greater thatn 10MEV)	$560
E. Superficial X-ray	$170
Chiropractic	$210
Podiatry	$170
Veterinary Medicine	$150
Industrial Radiography	$560
Accelerators (Industrial and Research)	$350
Education and Research	$350

Other Registration Fees and Services	Annual Service Fees (In U.S. dollars)
X-ray Services and Installers	$350
Radiation T Training Courses	$230
X-ray Sales and Demonstrations	$350
combined Sales and Service (Assembler)	$460
Dosimeterists and Physicists	$230
Shielding Evaluations (Routine)	$350 Per Evaluation
Shielding Evaluations (Nonroutine)	Full Cost
Reciprocity (X-ray producing Machines)	$350 Per Year Per Machine

Appendix B
2013 Schedule Of Fees For Registration
Certification And Inspecton

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed in the x-ray program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase. Thereafter, the fees will be adjusted on an annual basis to account for any change in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next year's fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	$170
Medical:	
A. Radiographic machine (including computer tomography)	$260
B. Fluoroscopic Machine	$400
C. Combined Radiographic-Fluoroscopic	$530
D. (1) Therapeutic: Linear Accelerator (Less that 10MEV)	$400
(2) Therapeutic: Linear Accelerator (Greater thatn 10MEV)	$640
E. Superficial X-ray	$200
Chiropractic	$240
Podiatry	$200
Veterinary Medicine	$170
Industrial Radiography	$640
Accelerators (Industrial and Research)	$400
Education and Research	$400

Other Registration Fees and Services	Annual Service Fees (In U.S. dollars)
X-ray Services and Installers	$400
Radiation T Training Courses	$260
X-ray Sales and Demonstrations	$400
combined Sales and Service (Assembler)	$530
Dosimeterists and Physicists	$260
Shielding Evaluations (Routine)	$400 Per Evaluation
Shielding Evaluations (Nonroutine)	Full Cost
Reciprocity (X-ray producing Machines)	$400 Per Year Per Machine

Appendix B
2014 Schedule Of Fees For Registration
Certification And Inspecton

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed in the x-ray program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase. Thereafter, the fees will be adjusted on an annual basis to account for any change in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next year's fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	$200
Medical:	
A. Radiographic machine (including computer tomography)	$300
B. Fluoroscopic Machine	$460
C. Combined Radiographic-Fluoroscopic	$610
D. (1) Therapeutic: Linear Accelerator (Less that 10MEV)	$460
(2) Therapeutic: Linear Accelerator (Greater thatn 10MEV)	$740
E. Superficial X-ray	$230
Chiropractic	$280
Podiatry	$230
Veterinary Medicine	$200
Industrial Radiography	$740
Accelerators (Industrial and Research)	$460
Education and Research	$460

Other Registration Fees and Services	Annual Service Fees (In U.S. dollars)
X-ray Services and Installers	$460
Radiation T Training Courses	$300
X-ray Sales and Demonstrations	$460
combined Sales and Service (Assembler)	$610
Dosimeterists and Physicists	$300
Shielding Evaluations (Routine)	$460 Per Evaluation
Shielding Evaluations (Nonroutine)	Full Cost
Reciprocity (X-ray producing Machines)	$460 Per Year Per Machine

Appendix B
2015 Schedule Of Fees For Registration
Certification And Inspecton

Applications for registration of radiation machines and other regulatory services shall pay the following fees for each machine that they possess and use at their facilities. The fees for each machine that they possess and use at their facilities. The fees cover a three-year registration period and the renewal fee is the amount listed in the x-ray program's fees web page ( ). The included fee schedule is the base fee beginning [effective date of rules]. For five successive years, the fees shall increase. Thereafter, the fees will be adjusted on an annual basis to account for any change in the consumer price index published by the department of labor, as of the close of the twelve-month period ending on August 31 of each calendar year. The next year's fee schedule will be posted on the radioactive material programs web site no later than thirty days after the index is published.

Registration Category	Fee/Machine (in U.S. dollars)
Dentistry	$230
Medical:	
A. Radiographic machine (including computer tomography)	$350
B. Fluoroscopic Machine	$530
C. Combined Radiographic-Fluoroscopic	$700
D. (1) Therapeutic: Linear Accelerator (Less that 10MEV)	$530
(2) Therapeutic: Linear Accelerator (Greater thatn 10MEV)	$850
E. Superficial X-ray	$260
Chiropractic	$320
Podiatry	$260
Veterinary Medicine	$230
Industrial Radiography	$850
Accelerators (Industrial and Research)	$530
Education and Research	$530

Other Registration Fees and Services	Annual Service Fees (In U.S. dollars)
X-ray Services and Installers	$530
Radiation T Training Courses	$350
X-ray Sales and Demonstrations	$530
combined Sales and Service (Assembler)	$700
Dosimeterists and Physicists	$350
Shielding Evaluations (Routine)	$530 Per Evaluation
Shielding Evaluations (Nonroutine)	Full Cost
Reciprocity (X-ray producing Machines)	$530 Per Year Per Machine

CHAPTER 33-10-12 REPEALED

CHAPTER 33-10-12.1 ALL NEW

CHAPTER 33-10-12.1
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

33-10-12.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 39. 10 Code of Federal Regulations 39.1, 39.2, 39.11, 39.13, 39.15, 39.17, 39.31, 39.33, 39.35, 39.37, 39.39, 39.41, 39.43, 39.45, 39.47, 39.49, 39.51, 39.53, 39.55, 39.61, 39.63, 39.65, 39.67, 39.69, 39.71, 39.73, 39.75, 39.77, 39.91 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. All of the requirements in chapter 33-10-12.1 apply to both licensees and registrants. A reference in 10 Code of Federal Regulations part 39 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", a reference to "licensed material" includes "registered source of radiation" and a reference to "licensed radioactive materials" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to article 33-10 and North Dakota Century Code chapter 23-20.1. "Registration" means the notification of the North Dakota department of health 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.

2. Where the words "NRC", "commission", "NRC regional office", appear in 10 Code of Federal Regulations part 39, substitute the words "North Dakota department of health".

3. Requirements in 10 Code of Federal Regulations 39 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations 39.

5. For references to 10 Code of Federal Regulations part 170, see 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-13 REPEALED

CHAPTER 33-10-13.1 ALL NEW

CHAPTER 33-10-13.1
PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Section
33-10-13.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 71

33-10-13.1-01. Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 71. 10 Code of Federal Regulations 71.0, 71.3, 71.4, 71.5, 71.7, 71.8, 71.9, 71.10, 71.12, 71.13, 71.14, 71.15, 71.17, 71.20, 71.21, 71.22, 71.23, 71.47, 71.81, 71.83, 71.85, 71.87, 71.88, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137 and appendix A to part 71 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations 71.0 (d), 71.14 (b), 71.101 (c)(2), (d) and (e).

2. Requirements in 10 Code of Federal Regulations 71 that apply to "licensed material" or "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission" or "administrator of the appropriate regional office" appear in 10 Code of Federal Regulations part 71, substitute the words "North Dakota department of health" except when used in 10 Code of Federal Regulations 71.5 (b), 71.10, 71.17 (b), (c)(3), (e), 71.85 (c), 71.88 (a)(4), 71.93 (c), 71.95, 71.97 (c), (c)(3)(iii), (f), and 71.101 (c)(1).

4. 10 Code of Federal Regulations 71.9 Employee Protection also applies to violations of North Dakota Century Code chapters 23-20 and 23-20.1.

5. State form number 8414, "notice to employees", must be posted instead of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations 71.

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

CHAPTER 33-10-14 REPEALED

CHAPTER 33-10-14.1 ALL NEW

CHAPTER 33-10-14.1
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

33-10-14.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 36

33-10-14.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 36. 10 Code of Federal Regulations 36.1, 36.2, 36.11, 36.13, 36.15, 36.17, 36.19, 36.21, 36.23, 36.25, 36.27, 36.29, 36.31, 36.33, 36.35, 36.37, 36.39, 36.41, 36.51, 36.53, 36.55, 36.57, 36.59, 36.61, 36.63, 36.65, 36.67, 36.69, 36.81 and 36.83 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Requirements in 10 Code of Federal Regulations 36 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

2. Where the words "NRC", "commission", or "NRC regional office" appear in 10 Code of Federal Regulations part 36, substitute the words "North Dakota department of health".

3. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations 36.

5. For references to 10 Code of Federal Regulations 170 and 171, see 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-09.1

CHAPTER 33-10-15 ALL NEW

Chapter 33-10-15
Therapeutic Radiation Machines

33-10-15-01. Scope.

1. This chapter establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this chapter are in addition to, and not in substitution for, other applicable provisions of these regulations.

2. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by subsection 33-10-15-03.3.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

33-10-15-02. Definitions. As used in this chapter, the following definitions apply:

1. "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of

the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

2. "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

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

4. "Accessible surface" means surface of equipment or of an equipment part that can be touched by persons without the use of a tool.

5. "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).

6. "Added filtration" means any filtration which is in addition to the inherent filtration.

7. "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

8. "Barrier" see "Protective barrier".

9. "Beam axis" means the axis of rotation of the beam limiting device from the source through the centers of the X-ray field.

10. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the useful beam.

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

12. "Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

13. "Bent beam linear accelerator" means a linear accelerator

geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

14. "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.

15. "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.

16. "CFR" means Code of Federal Regulations.

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

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

19. "Department" means the North Dakota department of health.

20. "Detector" (See "radiation detector").

21. "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.

22. "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.

23. "Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

24. "Electron applicator" means any accessory device utilized

during electron therapy which determines the extent of the treatment area at a given distance from the source.

25. "Entrance" 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.

26. "Exposure" means being exposed to ionizing radiation or to radioactive material.

27. "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

28. "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

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

30. "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

31. "Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to one joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. [1 Gy=100 rad].

32. "Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

33. "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.

34. "Individual" means any human being.

35. "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.

36. "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

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

38. "Irradiation" means the exposure of a living being or matter to ionizing radiation.

39. "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

40. "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

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

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

    a. The useful beam; and

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

43. "Light field" means the area illuminated by light, simulating the radiation field.

44. "mA" means milliampere.

45. "Medical use" means the intentional internal or external administration of radiation or radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in chapter 33-10-07.2.

46. "Megavolt (MV) [mega electron volt (MeV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]

47. "Monitor unit (MU)" (See "Dose monitor unit").

48. "Monitoring" means the measurement of radiation 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.

49. "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

50. "Nominal treatment distance" means:

    a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

    b. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

51. "Patient" means an individual or animal subjected to radiation for the purposes of diagnosis, or treatment.

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

53. "Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

54. "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.

55. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to absorption and scattering of the ionizing radiation in question.

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

57. "Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical electron beam dosimetry: report of AAPM radiation therapy committee task group 25" [Medical Physics 18(1): 73-109, Jan/Feb. 1991] and ICRU report 35, "Radiation dosimetry: electron beams with energies between 1 and 50 MeV", International commission on radiation units and measurements, September 15, 1984.

58. "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

59. "Primary protective barrier" see "Protective barrier".

60. "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

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

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

61. "Qualified expert" means an individual having the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American board of 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.

62. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of on hundred erg per gram or one one-hundredth joule per kilogram (0.01 gray).

63. "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.

64. "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.

65. "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 radiation exposure is the coulomb per kilogram (C/kg). (See section 33-10-01-14 units of exposure, dose, and activity for the special unit equivalent "roentgen" (R).)

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

67. "Radiation field" see "Useful beam".

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

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

70. "Radiation therapy physicist" means an individual qualified in accordance with section 33-10-15-03.4.

71. "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. "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

73. "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.

74. "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.

75. "Rem" (see "sievert").

76. "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 or radioactive material. "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.

77. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

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

79. "Secondary protective barrier" see "Protective barrier".

80. "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

81. "Shutter" means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

82. "Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert. [1 Sv=100 rem].

83. "Source" means the region and/or material from which the radiation emanates.

84. "Source-skin distance (SSD)" see "Target-skin distance".

85. "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axis relative to the patient during irradiation.

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

87. "Target" means that part of an X-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

88. "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X-ray target and/or electron virtual source to the surface of the irradiated object or patient.

89. "Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

90. "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.

91. "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.

92. "Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

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

94. "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.

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

96. "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.

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

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

99. "X-ray tube" means any electron tube which is designed for conversion of electrical energy into X-ray energy.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

33-10-15-03. General administrative requirements.

1. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the department. The registrant or the registrant's agent shall ensure that the requirements of chapter 33-10-15 are met in the operation of the therapeutic radiation machine(s).

2. A therapeutic radiation machine that does not meet the provisions of these regulations shall not be used for irradiation of patients.

3. Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to section 33-10-15-06 or section 33-10-15-07 shall require the authorized user to be a physician who:

   a. Is certified in:

      (1) Radiology or therapeutic radiology by the American board of radiology; or

      (2) Radiation oncology by the American osteopathic board of radiology; or

(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 radiation techniques applicable to the use of an external beam radiation therapy 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 shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology.

(2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(a) Review of the full calibration measurements and periodic quality assurance checks;

(b) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;

(c) Using administrative controls to prevent misadministrations;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(e) Checking and using radiation survey meters.

(3) To satisfy the requirement for a period of

supervised clinical experience, training shall 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. The supervised clinical experience shall include:

(a) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(b) Selecting proper dose and how it is to be administered;

(c) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

(d) Post-administration follow-up and review of case histories.

c. Notwithstanding the requirements of subdivision 33-10-15-03.3.a and 33-10-15-03.3.b, the registrant for any therapeutic radiation machine subject to section 33-10-15-06 may also submit the training of the prospective authorized user physician for department review on a case-by-case basis.

d. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the facility and is determined to meet the requirements.

4. Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to section 33-10-15-06 or 33-10-15-07 shall require the radiation therapy physicist to:

a. Be registered with the department, under the provisions

of chapter 33-10-02 of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified or eligible for certification by the American board of radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

c. Be certified or eligible for certification by the American board of medical physics in radiation oncology physics; or

d. Be certified or eligible for certification by the Canadian college of medical physics; or

e. 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 radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 33-10-15-04.2, 33-10-15-06.16, 33-10-15-07.20 and 33-10-15-06.17, 33-10-15-07-21 under the supervision of a radiation therapy physicist during the year of work experience.

5. Qualifications of operators.

a. Individuals who will be operating a therapeutic radiation machine for medical use shall be American registry of radiologic technologists (ARRT) registered radiation therapy technologists. Individuals who are not ARRT registered radiation therapy technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the joint review committee on education in radiologic technology.

b. The names and training of all personnel currently

operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

6. Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

7. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who meets the requirements of subsection 33-10-15-03.3. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

8. Visiting authorized user. Notwithstanding the provisions of subsection 33-10-15-03.7, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's certificate of registration for up to sixty days per calendar year under the following conditions:

   a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee; and

   b. The visiting authorized user meets the requirements established for authorized user(s) in subdivisions 33-10-15-03.3.a and 33-10-15-03.3.b; and

   c. The registrant maintains copies of all records specified by subsection 33-10-15-03.8 for five years from the date of the last visit.

9. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of chapter 33-10-15, these individuals are also subject to the requirements of subsections 33-10-04.2-06.5 and 33-10-04.2-09.2 of these regulations.

10. Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the department:

    a. Report of acceptance testing;

    b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by chapter 33-10-15, as well as the name(s) of person(s) who performed such activities;

    c. Records of maintenance and/or modifications performed on the therapeutic radiation machine after **[INSERT EFFECTIVE DATE OF THESE REGULATIONS]**, as well as the name(s) of person(s) who performed such services;

    d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

11. Records retention. All records required by chapter 33-10-15 shall be retained until disposal is authorized by the department unless another retention period is specifically authorized in chapter 33-10-15. All required records shall be retained in an active file from at least the time of generation until the next department inspection. Any required record generated prior to the last department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the department authorizes final disposal.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

33-10-15-04. General technical requirements.

1. Protection surveys.

    a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with section 33-10-15-08. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a

qualified expert and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in subsection 33-10-04.2-06.1.a (10 CFR 20.1201) of these regulations; and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in subdivisions 33-10-04.2-07.1.a (10 CFR 20.1301(a)) and 33-10-04.2-07.1.b of (10 CFR 20.1301(b)) these regulations.

b. In addition to the requirements of subdivision 33-10-15.04.1.a, a radiation protection survey shall also be performed prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapeutic radiation machine within the treatment room;

(3) After relocating the therapeutic radiation machine; or

(4) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

c. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a qualified expert, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or 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 individual responsible for conducting the survey;

d. If the results of the surveys required by subdivision 33-10-15.04.1.a or 33-10-15.04.1.b indicate any radiation levels in excess of the respective limit specified in subdivision 33-10-15.04.1.a, the registrant 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 therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(2) Until the registrant has received a specific exemption from the department.

2. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by section 33-10-15-04.2 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by subdivisions 33-10-04.2-07.1.a (10 CFR 20.1301(a)) and 33-10-04.2-07.1.b (10 CFR 20.1301(b)) of these regulations, before beginning the treatment program the registrant shall:

a. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with subdivisions 33-10-04.2-07.1.a (10 CFR 20.1301(a)) and 33-10-04.2-07.1.b (10 CFR 1301(b)) of these regulations;

b. Perform the survey required by section 33-10-15-04.1 again; and

c. Include in the report required by subsection 33-10-15-04.4 the results of the initial survey, a description of the modification made to comply with subdivision 33-10-15-04.2.a, and the results of the second survey; or

d. Request and receive a registration amendment under subdivision 33-10-04.2-07.1.c (10 CFR 1301(c)) of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by subdivisions 33-10-04.2-07.1.a (10 CFR 1301(a)) and 33-10-04.2-07.1.b (10 CFR 1301(b)) of these regulations.

3. Dosimetry equipment.

a. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National institute for standards and technology (NIST) or by an American association of physicists in medicine (AAPM) Accredited dosimetry calibration laboratory (ADCL). The calibration shall have been performed within the previous twenty-four months and after any servicing that may have affected system calibration. An independent survey shall be conducted by a qualified expert or radiation therapy physicist other than the person performing the original survey prior to the equipment being used except as described in subdivision 33-10-15-04.1.d.

(1) For beams with energies greater than one million volts (1 Mv) or one million electron volts (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(2) For beams with energies equal to or less than one million volts (1 Mv) or one million electron volts (1 MeV), the dosimetry system shall have been calibrated at an energy appropriate for the radiation being measured;

b. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision 33-10-15-04.3.a. This comparison shall have been performed within the previous twelve months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in subdivision 33-10-15-04.3.a.;

c. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by subdivision 33-10-15-04.3.a. and subdivision 33-10-15-04.3.b.; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct

supervision and in the physical presence of, a radiation therapy physicist.

4. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to sections 33-10-15-06 or 33-10-15-07 shall furnish a copy of the records required in subsections 33-10-15-04.1 and 33-10-15-04.2 to the department within 30 days following completion of the action that initiated the record requirement.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

Chapter 33-10-15-05. Quality management program. The facility shall implement a quality management program. The facility may use the quality management programs found in either Appendix B or Appendix C.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

Chapter 33-10-15-06. Therapeutic radiation machines of less than five hundred kilovolts.

1. Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kilovolts, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

   a. Five to fifty kilovolts systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one milligray (100 mrad) in any one hour.

   b. Greater than fifty and less than five hundred kilovolts systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one centagray (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters. In addition, the air kerma rate at a distance of five

centimeters from the surface of the tube housing assembly shall not exceed thirty centagray (30 rad) per hour.

c. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions 33-10-15-06.1.a and 33-10-15-06.1.b for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.

2. Permanent beam limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

3. Adjustable or removable beam limiting devices.

a. All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used;

b. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

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

a. Filters can not be accidentally displaced at any possible tube orientation;

b. An interlock system prevents irradiation if the proper filter is not in place;

c. The air kerma rate escaping from the filter slot shall not exceed one centagray (1 rad) per hour at one meter under any operating conditions; and

d. Each filter shall be marked as to its material of construction and its thickness. For wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray).

5. Tube immobilization.

a. The X-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing

aperture; and

b. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

6. Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

7. Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to five tenths millimeters of lead at one hundred kilovolts, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

8. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

a. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

b. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" 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;

c. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

d. The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

e. The timer shall not permit an exposure if set at zero;

f. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

g. Timer shall be accurate to within one percent of the selected value or one second, whichever is greater.

9. Control panel functions. The control panel, in addition to the displays required by other provisions in section 33-10-15-06, shall have:

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

   b. An indication of whether X-rays are being produced;

   c. A means for indicating X-ray tube potential and current;

   d. The means for terminating an exposure at any time;

   e. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

   f. A positive display of specific filter(s) in the beam.

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

   a. It shall be possible to activate only one X-ray tube at any time;

   b. There shall be an indication at the control panel identifying which X-ray tube is activated; and

   c. There shall be an indication at the tube housing assembly when that tube is energized.

11. Target-to-skin distance (TSD). There shall be a means of determining the central axis target-to-skin distance to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

12. Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

13. Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration

window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

14. Facility design requirements for therapeutic radiation machines capable of operating in the range fifty kilovolts to five hundred kilovolts. In addition to shielding adequate to meet requirements of section 33-10-15-09, the treatment room shall meet the following design requirements:

    a. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

    b. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

15. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above one hundred fifty kilovolts shall meet the following additional requirements:

    a. All protective barriers shall be fixed except for entrance doors or beam interceptors;

    b. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

    c. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall 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; and

    d. When any door referred to in subdivision 33-10-15-06.15.c is opened while the X-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one milligray (100 mrad)

per hour.

16. Full calibration measurements.

a. Full calibration of a therapeutic radiation machine subject to section 33-10-15-06 shall be performed by, or under the direct supervision of, a radiation therapy physicist:

(1) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(2) At intervals not exceeding one year; and

(3) Before medical use under the following conditions:

(a) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(4) Notwithstanding the requirements of paragraph 33-10-15-06.16.a(3):

(a) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and

(b) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in subparagraph 33-10-15-06.16.a(3)(a).

b. To satisfy the requirement of subdivision 33-10-15-06.16.a, full calibration shall include all measurements

recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and gamma ray beams for radiation therapy in the energy range ten keV to fifty MeV" (1981).

c. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

17. Periodic quality assurance checks.

a. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to section 33-10-15-06, which are capable of operation at greater than or equal to fifty kilovolts.

b. To satisfy the requirement of subdivision 33-10-15-06.17.a, quality assurance checks shall meet the following requirements:

(1) The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

(2) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subdivision 33-10-15-06.16.a. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subdivision 33-10-15-06.16.a, shall be stated.

c. The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient irradiation;

d. Whenever a quality assurance check indicates a significant change in the operating characteristics of a

system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in subdivision 33-10-15-06.16.a;

e. The registrant shall use the dosimetry system described in subdivision 33-10-15-04.3.b to make the quality assurance check required in subdivision 33-10-15-06.17.b;

f. The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed;

g. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to section 33-10-15-06 are performed at intervals not to exceed one month;

h. Notwithstanding the requirements of subdivision 33-10-15-06.17.f and 33-10-15-06.17.g, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by subdivision 33-10-15-06.17.f and 33-10-15-06.17.g have been performed within the 30 day period immediately prior to said administration;

i. To satisfy the requirement of subdivision 33-10-15-06.17.g, safety quality assurance checks shall ensure proper operation of:

(1) Electrical interlocks at each external beam radiation therapy room entrance;

(2) The "BEAM-ON" and termination switches;

(3) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

(4) Viewing systems;

(5) If applicable, electrically operated treatment room doors from inside and outside the treatment room;

j. The registrant shall maintain a record of each quality assurance check required by subdivision 33-10-15-06.17.g for three years. The record shall include: the date of the quality assurance check; the manufacturer's name,

model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

18. Operating procedures.

    a. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subsections 33-10-15-06.16 and 33-10-15-06.17 have been met;

    b. Therapeutic radiation machines shall not be left unattended unless secured pursuant to subdivision 33-10-15-06.1.e;

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

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

    e. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

    f. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above one hundred fifty kilovolts. At energies less than or equal to one hundred fifty kilovolts, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of subsection 33-10-04.2-06.1 (10 CFR 20.1201) of these regulations.

19. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with section 33-10-15-06 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation

measurement survey instrument capable of measuring dose rates over the range ten microsievert (1 mrem) per hour to ten millisievert (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with section 33-10-15-08.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

33-10-15-07. Therapeutic radiation machines - photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

1. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with section 33-10-15-07 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten microsievert (1 mrem) per hour to ten millisievert (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with section 33-10-15-08.

2. Leakage radiation outside the maximum useful beam in photon and electron modes.

   a. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of two tenths percent and an average of one tenth percent of the absorbed dose on the beam axis at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters at a minimum of sixteen points uniformly distributed in the plane;

   b. Except for the area defined in subdivision 33-10-15-07.2.a, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed five tenths percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be

averaged over an area not exceeding one hundred square centimeters;

c. For equipment manufactured after **[INSERT EFFECTIVE DATE OF THESE REGULATIONS]**, the neutron absorbed dose outside the useful beam shall be in compliance with International electrotechnical commission (IEC) document 601-2-1 (most current revision); and

d. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions 33-10-15-07.2.a and 33-10-15-07.2.c for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.

3. Leakage radiation through beam limiting devices.

a. Photon radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field;

b. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(1) A maximum of two percent and average of five tenths percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(2) A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the

useful beam.

c. Measurement of Leakage Radiation.

(1) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

(2) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

4. Filters/Wedges.

a. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

b. If the absorbed dose rate information required by subsection 33-10-15-07.1 relates exclusively to operation with a field-flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

c. For equipment which utilizes wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering foils:

(1) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no

filter" has been made at the treatment control panel, either manually or automatically;

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

(3) A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

(4) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

5. Stray Radiation in the Useful Beam. For equipment manufactured after **[INSERT EFFECTIVE DATE OF THESE REGULATIONS]**, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International electrotechnical commission (IEC) document 601-2-1 (most current revision).

6. Beam Monitors. All therapeutic radiation machines subject to section 33-10-15-07 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

a. Equipment shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

b. The detector and the system into which that detector is incorporated shall meet the following requirements:

(1) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

(2) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(3) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(4) The design of the beam monitoring systems shall ensure that the:

(a) Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

(b) Failure of either system shall terminate irradiation or prevent the initiation of radiation.

(5) Each beam monitoring system shall have a legible display at the treatment control panel. Each display shall:

(a) Maintain a reading until intentionally reset;

(b) Have only one scale and no electrical or mechanical scale multiplying factors;

(c) Utilize a design such that increasing dose is displayed by increasing numbers; and

(d) In the event of power failure, the beam monitoring information required in subparagraph 33-10-15-07.6.e(5)(c) 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.

7. Beam Symmetry.

a. Bent-beam linear accelerators subject to section 33-10-15-07 shall be provided with auxiliary device(s) to monitor beam symmetry;

b. The device(s) referenced in subdivision 33-10-15-07.7.a shall be able to detect field asymmetry greater than five percent; and

c. The device(s) referenced in subdivision 33-10-15-07.7.a shall be configured to terminate irradiation if the specifications in subdivision 33-10-15-07.7.b can not be maintained.

8. Selection and Display of Dose Monitor Units.

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

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

c. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

d. After termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

9. Air Kerma Rate/Absorbed Dose Rate. A system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. [The radiation detectors specified in subsection 33-10-15-07.6 may form part of this system.] In addition:

a. The dose monitor unit rate shall be displayed at the treatment control panel;

b. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

c. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the

specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four gray (400 rad); and

d. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in subdivisions 33-10-15-07.1.b and 33-10-15-07.1.c for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the department.

10. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

a. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

b. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen percent or forty dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

c. An indicator on the control panel shall show which monitoring system has terminated irradiation.

d. For new equipment, a secondary 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 secondary dose monitoring system.

11. Termination of irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

12. Interruption of irradiation. It shall be possible to interrupt irradiation and equipment movements at any time from 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 pre-selected value during an interruption,

irradiation and equipment movements shall be automatically terminated.

13. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

    a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

    b. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" 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;

    c. After termination of irradiation and before irradiation can be reinitiated, it shall be necessary to reset the preset time selector.

    d. The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

14. Selection of Radiation Type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

    a. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

    b. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

    c. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

    d. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted;

    e. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

f. 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.

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

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

b. 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.

c. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

d. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

e. 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.

f. For equipment manufactured after **[INSERT EFFECTIVE DATE OF THESE REGULATIONS]**, the selection of energy shall be in compliance with International electrotechnical commission (IEC) document 601-2-1 (most current revision).

16. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

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

b. The mode of operation shall be displayed at the treatment control panel;

c. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

d. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

e. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement.

(1) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one cm of linear motion differs by more than twenty percent from the selected value;

(2) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent from the dose monitor unit value selected;

(3) An interlock shall be provided to prevent motion of more than five degrees or one cm beyond the selected limits during moving beam radiation therapy;

(4) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(5) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

f. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by subsection 33-10-15-07.10; and

g. An interlock system shall be provided to terminate irradiation if movement:

(1) Occurs during stationary beam radiation therapy; or

(2) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

17. Facility design requirements for therapeutic radiation machines operating above five hundred kilovolts. In addition to shielding adequate to meet requirements of section 33-10-15-09, the following design requirements are made:

a. Protective Barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

b. Control Panel. In addition to other requirements specified in chapter 33-10-15, the control panel shall also:

(1) Be located outside the treatment room;

(2) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(3) Provide an indication of whether radiation is being produced; and

(4) Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

c. Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

d. Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for

irradiation of patients unless continuous two-way aural communication is possible;

e. Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

f. Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

g. Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with subdivisions 33-10-04.2-07.1.a (10 CFR 1301(a)) and 33-10-04.2-07.1.b (10 CFR 1301(b)) of these regulations, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

h. Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subsection 33-10-15-07.11. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

i. Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

j. Surveys for Residual Radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten million volts prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-

neutron production.

18. Radiation therapy physicist support.

a. The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of five hundred kilovolts and above. The radiation therapy physicist shall be responsible for:

(1) Full calibration(s) required by subsection 33-10-15-07.20 and protection surveys required by subsection 33-10-15-04.1;

(2) Supervision and review of dosimetry;

(3) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

(4) Quality assurance, including quality assurance check review required by subdivision 33-10-15-07.21.e.

(5) Consultation with the authorized user in treatment planning, as needed; and

(6) Perform calculations/assessments regarding misadministrations.

b. If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by subsection 33-10-15-07.17 shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

19. Operating procedures.

a. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

b. Therapeutic radiation machines shall not be made available for medical use unless the requirements of 33-10-15-04.1, 33-10-15-07.20 and 33-10-15-07.21 have been met;

c. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

d. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

e. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

f. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

20. Acceptance testing, commissioning and full calibration measurements.

a. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to section 33-10-15-07 shall be performed by, or under the direct supervision of, a radiation therapy physicist.

b. Acceptance testing and commissioning shall be performed in accordance with "American association of physicists in medicine code of practice for radiotherapy accelerators: report of American association of physicists in medicine radiation therapy task group 45" and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

c. Full calibration shall include measurement of all parameters required by table II of "Comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40" and shall be performed in accordance with "American association of physicists in medicine code of practice for radiotherapy accelerators: report of American association of physicists in medicine radiation therapy task group 45". Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding twelve calendar months, unless a more frequent interval is required in table II.

d. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine

that all parameters are within acceptable limits:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and

(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in paragraph 33-10-15-07.20.d(1).

e. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

21. Periodic quality assurance checks.

a. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to section 33-10-15-07 at intervals not to exceed those specified in "Comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40";

b. To satisfy the requirement of subdivision 33-10-15-07.21.a, quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for radiation

oncology: report of American association of physicists in medicine radiation therapy committee task group 40". Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed twelve consecutive calendar months;

c. The registrant shall use a dosimetry system that has been inter-compared within the previous twelve months with the dosimetry system described in subdivision 33-10-15-04.3.a. to make the periodic quality assurance checks required in subdivision 33-10-15-07.21.b;

d. The registrant shall perform periodic quality assurance checks required by subdivision 33-10-15-07.21.a in accordance with procedures established by the radiation therapy physicist;

e. The registrant shall review the results of each periodic radiation output check according to the following procedures:

(1) The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

(2) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

(3) The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

f. Therapeutic radiation machines subject to section 33-10-15-07 shall have safety quality assurance checks listed in "Comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40" performed at intervals not to exceed one week;

g. To satisfy the requirement of subdivision 33-10-15-

07.21.e, safety quality assurance checks shall ensure proper operation of:

(1) Electrical interlocks at each external beam radiation therapy room entrance;

(2) Proper operation of the "BEAM-ON", interrupt and termination switches;

(3) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(4) Viewing systems;

(5) Electrically operated treatment room door(s) from inside and outside the treatment room;

(6) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

h. The registrant shall promptly repair any system identified in subdivision 33-10-15-07.21.g that is not operating properly; and

i. The registrant shall maintain a record of each quality assurance check required by subdivisions 33-10-15-07.21.a and 33-10-15-07-21.b for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

33-10-15.08. Calibration of Survey Instruments.

1. The registrant shall ensure that the survey instruments used to show compliance with chapter 33-10-15 have been calibrated before first use, at intervals not to exceed twelve months, and following repair.

2. To satisfy the requirements of subsection 33-10-15-08.1, the registrant shall:

   a. Calibrate all required scale readings up to ten millisievert (1000 mrem) per hour with an appropriate radiation source that is traceable to the National institute of standards and technology (NIST);

   b. Calibrate at least two points on each scale to be calibrated. These points should be at approximately one-third and two-thirds of full-scale; and

3. To satisfy the requirements of subsection 33-10-15-08.2, the registrant shall:

   a. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and

   b. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty percent if a correction factor or graph is conspicuously attached to the instrument.

4. The registrant shall retain a record of each calibration required in subsection 33-10-15-08.1 for three years. The record shall include:

   a. A description of the calibration procedure; and

   b. 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.

5. The registrant may obtain the services of individuals registered by the department, or licensed by the United States nuclear regulatory commission, an agreement state, or a licensing state to perform calibrations of survey instruments.

Records of calibrations that contain information required by subsection 33-10-15-08.4 shall be maintained by the registrant.

History: Effective
General Authority: NDCC 23-10.1-02
Law Implemented: NDCC 23-20.1-03

33-10-15-09. Shielding and safety design requirements.

1. Each therapeutic radiation machine subject to section 33-10-15-06 or 33-10-15-07 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with subsection 33-10-04.2-06.1 (10 CFR 20.1201) and 33-10-04.2-07.1 (10 CFR 20.1301) of these regulations.

2. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix A to chapter 33-10-15.

APPENDIX A
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

1. All Therapeutic Radiation Machines.

   a. Basic facility information including: name, telephone number and department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

   b. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

   c. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

2. Therapeutic Radiation Machines up to 150 Kv (photons only). In addition to the requirements listed in subsection 1 above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kilovolts shall submit shielding plans which contain, as a minimum, the following additional information:

   a. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

   b. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

   c. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on

the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with subsection 33-10-04.2-06.1 (10 CFR 20.1201) of these regulations;

d. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

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

f. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, please also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

3. Therapeutic Radiation Machines Over 150 kilovolts.

In addition to the requirements listed in subsection 1 above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kilovolts and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

a. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [i.e.: photon, electron]. The target to isocenter distance shall be specified;

b. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated

number of patients to be treated per day or week;

c. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze;

d. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

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

f. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas; and

g. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility:

   (1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date; and

   (2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

4. Neutron Shielding

In addition to the requirements listed in subsection 3 above, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

a. The structural composition, thickness, minimum density and location of all neutron shielding material;

b. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

c. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:

   (1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

   (2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

d. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

5. References

a. NCRP Report 147, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (2004).

b. NCRP Report 144, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (2003).

c. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

APPENDIX B
QUALITY MANAGEMENT PROGRAM

1. In addition to the definitions in section 33-10-15-02, the following definitions are applicable to this appendix B:

   a. "Misadministration" means the administration of an external beam radiation therapy dose:

      (1) Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

      (2) When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

      (3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

      (4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

   b. "Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique;

   c. "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

   d. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

2. Scope and Applicability. Each applicant or registrant subject to sections 33-10-15-06 or 33-10-15-07 shall establish and

maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

a. Prior to administration, a written directive is prepared for any external beam radiation therapy dose;

(1) Notwithstanding subdivision 2.a of appendix B, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(2) Notwithstanding subdivision 2.a of appendix B, 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 shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(3) Notwithstanding subdivision 2.a of appendix B, 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 shall 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 and signed by an authorized user within 24 hours of the oral directive.

b. Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

d. Each administration is in accordance with the written directive; and

e. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

3. Development of Quality Management Program.

a. Each application for registration subject to sections 33-10-15-06 or 33-10-15-07 shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by chapter 33-10-02 of these regulations. The registrant shall implement the program upon issuance of a certificate of registration by the department;

b. Each existing registrant subject to sections 33-10-15 or 33-10-15-07 shall, within 30 days of **[INSERT EFFECTIVE DATE OF THESE REGULATIONS]**, submit to the department a written certification that a quality management program has been implemented.

4. As a part of the quality management program, the registrant shall:

a. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;

b. Conduct these reviews at intervals not to exceed 12 months;

c. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of subsection 2; and

d. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for 3 years.

5. The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable

event by:

a. Assembling the relevant facts including the cause;

b. Identifying what, if any, corrective action is required to prevent recurrence; and

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

6. The registrant shall retain:

a. Each written directive; and

b. A record of each administered radiation dose, in an auditable form, for 3 years after the date of administration.

7. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

8. The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:

a. Notify the department by telephone no later than the next calendar day after discovery of the misadministration;

b. Submit a written report to the department within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

c. Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will

inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

d. Retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and

e. If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the department, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the department can be obtained from the registrant;

9. Aside from the notification requirement, nothing in subsection 33-10-15-05.8 affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

APPENDIX C
ALTERNATIVE QUALITY MANAGEMENT PROGRAM

1. In addition to the definitions in section 33-10-15-02, the following definitions are applicable to this appendix C:

   a. "Misadministration" means the administration of an external beam radiation therapy dose:

      (1) Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

      (2) When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

      (3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

      (4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

   b. "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

   c. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

2. Each registrant shall establish and maintain a written program to provide assurance that radiation is administered to humans as directed by the authorized user. The program shall include the following elements:

   a. Procedure for preparing written directives for the administration of radiation, however, a written directive is not required when an authorized user personally administers a dosage provided the pertinent facts are documented as otherwise required;

b. Procedure for verifying by more than one method the identity of the individual to be administered radiation;

c. Procedure for updating the therapy operating and emergency procedures manual;

d. Procedure for verifying that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

e. Procedures assuring that administration of radiation is carried out as specified in the written directive or the therapy operating and emergency procedures manual;

f. Procedures for identifying and evaluating unintended deviations from the written directive or the therapy operating and emergency procedures manual including taking appropriate action for recordable events and misadministrations;

3. Each registrant shall evaluate each administrative and shall take the following actions in response to a misadministration:

a. Notify the Department by telephone no later than the next calendar day after discovery of the misadministration;

b. Submit a written report to the Department within 15 days after discovery of the misadministration. The written report shall include: the registrants's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

c. Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgement,

telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary medical care as a result of the misadministrations, because of any delay in notification;

d. Retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number of identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the action taken to prevent recurrence; and

e. If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the Department, or a brief description of both the event and the consequences as they may effect the report submitted to the Department can be obtained from the registrant.

4. Each registrant shall evaluate and respond to recordable events within 30 days after discovery by assembling the relevant facts, identifying the cause of the recordable event, and taking appropriate action, if any is required, to prevent recurrence.

5. Each registrant shall conduct an annual evaluation of the human administration program including any recommendations for changes to be made as well as any modifications made since the last evaluation and, if required, revise procedures to assure that the radiation is administered as directed by the authorized user. Modifications made to the program shall not decrease the effectiveness of the program.

6. Each registrant shall retain, in auditable form, for 3 years:

a. Each written directive;

b. A record of each administered radiation dose where a

written directive is required;

c. A record of each annual review of the program including the evaluations and findings of the review;

d. A record of each recordable event, the relevant facts, and any corrective actions taken.

CHAPTER 33-10-16 ALL NEW

CHAPTER 33-10-16
DOMESTIC LICENSING OF SOURCE MATERIAL

Section
33-10-16-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 40

33-10-16-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 40. 10 Code of Federal Regulations 40.1, 40.2, 40.3, 40.4, 40.7, 40.9, 40.10, 40.11, 40.12, 40.13, 40.14, 40.20, 40.21, 40.22, 40.25, 40.26, 40.31, 40.32, 40.34, 40.35, 40.36, 40.41, 40.42, 40.43, 40.44, 40.45, 40.46, 40.51, 40.60, 40,61, 40.62, 40.63, 40.65, 40.71 and appendix A to part 40 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations 40.12 (b), 40.31 (j), (k) and (l), 40.32 (d) and (g) and those portions of paragraph (e) which apply to uranium enrichment and uranium hexafluoride facilities, 40.41 (d),(e)(1), (e)(3), and (g), 40.51 (b)(6); appendix A, criterion 11A through F and criterion 12.

2. Requirements in 10 Code of Federal Regulations 40 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional administrator" or "administrator of the appropriate regional office" appear in 10 Code of Federal Regulations part 40, substitute the words "North Dakota department of health" except when used in 10 Code of Federal Regulations 40.11.

4. 10 Code of Federal Regulations 40 Employee Protection also applies to violations of North Dakota Century Code chapters 23-20 and 23-20.1.

5. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

6. North Dakota state form number 8414, "notice to employees", must be posted instead of NRC form 3 that is specified in 10 Code of Federal Regulations 40.

7. North Dakota state form Number 16092 "Registration Certificate: Use of Depleted Uranium Under General License" must be used instead of nuclear regulatory commission form 244 that is specified in 10 Code of Federal Regulations 40.

8. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations 40.

9. North Dakota state form number 18941 "Certificate: Disposition of Radioactive Material" must be used instead of NRC form 314 as specified in 10 Code of Federal Regulations 40.

10. For references to 10 Code of Federal Regulations parts 170 and 171, see chapter 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-17 ALL NEW

CHAPTER 33-10-17
DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

Section
33-10-17-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations Part 70

33-10-17-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 70. 10 Code of Federal Regulations 70.1, 70.2, 70.3, 70.4, 70.7, 70.9, 70.10, 70.11, 70.12, 70.17, 70.18, 70.19, 70.20, 70.21, 70.22, 70.23, 70.25, 70.31, 70.32, 70.33, 70.34, 70.35, 70.36, 70.38, 70.39, 70.41, 70.42, 70.50, 70.51, 70.56 and 70.81 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. The following are not adopted by reference: 10 Code of Federal Regulations 70.1(c),(d) and (e), 70.20a, 70.20b, 70.21(a)(1), (c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (a)(7), (a)(8), (a)(9), (a)(10), (a)(11), (a)(12) and (b), 70.23a, 70.25(a)(1), 70.31(c), (d) and (e), 70.32(a)(1), (a)(4), (a)(5), (a)(6), (a)(7), (b)(1), (b)(3), (b)(4), (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.42(b)(6) and 70.51(c).

2. Requirements in 10 Code of Federal Regulations 70 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission", "NRC regional administrator", "NRC regional office", "administrator of the appropriate nuclear regulatory commission's regional office", "administrator of the appropriate regional office" or "Nuclear regulatory commission's office of nuclear material safety and safeguards, division of industrial and medical nuclear safety" appear in 10 Code of Federal Regulations part 70, substitute the words "North Dakota department of health".

4. 10 Code of Federal Regulations 70.7 Employee Protection also applies to violations of North Dakota Century Code chapters 23-20 and 23-20.1.

5. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

6. North Dakota state form number 8418, "application for radioactive material license", must be used instead of nuclear regulatory commission form 313 as specified in 10 Code of Federal Regulations 70.

7. North Dakota state form number 8414, "notice to employees", must be posted instead of United States nuclear regulatory commission form 3 that is specified in 10 Code of Federal Regulations 70.

8. For references to 10 Code of Federal Regulations part 170, section 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-18 ALL NEW

CHAPTER 33-10-18
GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

33-10-18-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 31. 10 Code of Federal Regulations 31.1, 31.2, 31.3, 31.5, 31.6, 31.7, 31.8, 31.9, 31.10, 31.11, 31.12 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference are 10 Code of Federal Regulations 31.3 (b) and (c) and 31.6 (a).

2. Requirements in 10 Code of Federal Regulations 31 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States nuclear regulatory commission" or "director of nuclear material safety and safeguards" appear in 10 Code of Federal Regulations part 31, substitute the words "North Dakota department of health" except when used in 10 Code of Federal Regulations 31.8 (c)(2) and 31.11 (d)(2).

4. North Dakota state form number 8423, "Certificate - In Vitro Testing with Radioactive Material Under General License", must be used instead of nuclear regulatory commission form 483 as specified in 10 Code of Federal Regulations 31.

5. References in 10 Code of Federal Regulations 31 to specific licenses issued by an agreement state also include specific licenses issued by the United States nuclear regulatory commission.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-19 ALL NEW

CHAPTER 33-10-19
RECIPROCAL RECOGNITION OF LICENSES

Section
33-10-19-01 Adoption by Reference of Several Sections in 10 CFR Part 150

33-10-19-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 150. 10 Code of Federal Regulations 150.1, 150.2, 150.3, 150.11, 150.20, 150.31, 150.32 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 150.3 (Foreign Obligations).

2. Requirements in 10 Code of Federal Regulations 150 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "nuclear regulatory commission", "regional administrator", "United States nuclear regulatory commission", "region" or "regional administrator of the United States nuclear regulatory commission regional office" appear in 10 Code of Federal Regulations part 150, substitute the words "North Dakota department of health" except when used in 150.5.

4. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

5. North Dakota state form number 58230 "Radioactive Material Reciprocity Request" must be used instead of nuclear regulatory commission form 241 as specified in 10 Code of Federal Regulations 150.

6. Where the words "non-agreement states", "areas of exclusive rederal jurisdiction within agreement states" or "offshore waters" are used in 10 Code of Federal Regulations 150.20 (a)(1)(i), (ii), (iii), (b), (b)(3) and (b)(4) substitute the words "state of North Dakota".

7. Where the words "agreement state(s) license" are used in 10 Code of Federal Regulations 150.20 also add the words "nuclear regulatory commission license". Where the words "license issued by an agreement state" are used in 10 Code of Federal Regulations 150.20 also add the words "license issued by the nuclear regulatory commission".

Where the words "license from an agreement state" are used in 10 Code of Federal Regulations 150.20 also add the words "license from the nuclear regulatory commission".

8. The words "for the first time in a calendar year" are stricken from 10 Code of Federal Regulations 150.20 (b)(1).

9. For references to 10 Code of Federal Regulations part 170, section 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-20 ALL NEW

CHAPTER 33-10-20
SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

33-10-20-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 32. 10 Code of Federal Regulations 32.1, 32.2, 32.3, 32.13, 32.17, 32.24, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.59, 32.61, 32.62, 32.71, 32.72, 32.74, 32.101, 32.102, 32.103 and 32.110 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Not adopted by reference is 10 Code of Federal Regulations 32.1(c)(1).

2. Requirements in 10 Code of Federal Regulations 32 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

3. Where the words "NRC", "commission", "NRC regional office" or "director of nuclear material safety and safeguards" appear in 10 Code of Federal Regulations part 32, substitute the words "North Dakota department of health" except when used in 32.51(a)(3)(iii), 32.54(a), 32.58, 32.71 (d), 32.72 (b)(5), and 32.74(a)(3).

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of nuclear regulatory commission form 313 as specified in 10 Code of Federal Regulations 32.

5. For references to 10 Code of Federal Regulations part 170, section 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

CHAPTER 33-10-21 ALL NEW

CHAPTER 33-10-21
SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

33-10-21-01. Adoption by reference of several sections in 10 CFR part 33. 10 CFR 33.1, 33.11, 33.12, 33.13, 33.14, 33.15, 33.16, 33.17 and 33.100 are adopted by reference as they exist on January 1, 2010, with the following exceptions:

1. Requirements in 10 CFR 33 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.

2. Where the word "commission", appears in 10 CFR part 33, substitute the words "North Dakota department of health".

3. "Act" includes North Dakota Century Code chapters 23-20 and 23-20.1.

4. North Dakota state form number 8418, "application for radioactive material license", must be used instead of nuclear regulatory commission form 313 as specified in 10 CFR 33.

5. For references to 10 Code of Federal Regulations part 170, section 33-10-11 for applicable fee schedules.

History:
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.01-04