

ARTICLE 33-10

RADIOLOGICAL HEALTH RULES

Chapter	
33-10-01	General Provisions
33-10-02	Registration of Radiation Machine Facilities and Services
33-10-03	Licensing of Radioactive Material [Repealed]
33-10-03.1	Rules of General Applicability to Domestic Licensing of Byproduct Material
33-10-04	Standards for Protection Against Radiation [Repealed]
33-10-04.1	Standards for Protection Against Radiation [Repealed]
33-10-04.2	Standards for Protection Against Radiation
33-10-05	Radiation Safety Requirements for Industrial Radiographic Operations [Repealed]
33-10-05.1	Radiation Safety Requirements for Industrial Radiographic Operations
33-10-06	X-Rays in the Healing Arts
33-10-07	Use of Radionuclides in the Healing Arts [Repealed]
33-10-07.1	Medical Use of Radioactive Material [Repealed]
33-10-07.2	Medical Use of Byproduct Material
33-10-08	Radiation Safety Requirements for Analytical X-Ray Equipment
33-10-09	Radiation Safety Requirements for Particle Accelerators
33-10-10	Notices, Instructions, and Reports to Workers - Inspections [Repealed]
33-10-10.1	Notices, Instructions, and Reports to Workers - Inspections
33-10-11	Fees for Issuance of License and Registration Certificates and Inspections
33-10-12	Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies [Repealed]
33-10-12.1	Licenses and Radiation Safety Requirements for Well Logging
33-10-13	Transportation of Radioactive Material [Repealed]
33-10-13.1	Packaging and Transportation of Radioactive Material
33-10-14	Licenses and Radiation Safety Requirements for Irradiators [Repealed]
33-10-14.1	Licenses and Radiation Safety Requirements for Irradiators
33-10-15	Therapeutic Radiation Machines
33-10-16	Domestic Licensing of Source Material
33-10-17	Domestic Licensing of Special Nuclear Material
33-10-18	General Domestic Licenses for Byproduct Material
33-10-19	Reciprocal Recognition of Licenses
33-10-20	Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material
33-10-21	Specific Domestic Licenses of Broad Scope for Byproduct Material

**CHAPTER 33-10-01
GENERAL PROVISIONS**

Section	
33-10-01-01	Purpose
33-10-01-02	Scope
33-10-01-03	Authority
33-10-01-04	Definitions
33-10-01-05	Exemptions
33-10-01-06	Records
33-10-01-07	Inspections
33-10-01-08	Tests
33-10-01-09	Additional Requirements
33-10-01-10	Violations
33-10-01-11	Impounding
33-10-01-12	Prohibited Uses
33-10-01-13	Communications
33-10-01-14	Units of Exposure, Dose, and Activity

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 state department of health has been authorized to provide and administer this article under the provisions of North Dakota Century Code chapter 23-20.1.

History: Amended effective July 1, 1995.

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. "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.
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).
3. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).
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.
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.
6. "CFR" means Code of Federal Regulations.
7. "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids, and polycarboxylic acids (e.g., citric acid, carboic acid, and gluconic acid).

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).
9. "Department" means the North Dakota state department of health.
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.
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.
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.
13. "Exposure" means being exposed to ionizing radiation or to radioactive material.
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].
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.
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.
17. "Human use" means the internal or external administration of radiation or radioactive material to human beings.
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.
19. "License" means a general or specific license issued by the department in accordance with the regulations adopted by the department.

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.
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, incorporated.
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.
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.
24. "Natural radioactivity" means radioactivity of naturally occurring nuclides.
25. "Nuclear regulatory commission (NRC)" means the United States nuclear regulatory commission or its duly authorized representatives.
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.
27. "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.
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.
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].

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.
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 exposure is the coulomb per kilogram (C/kg). (See section 33-10-01-14 units of radiation exposure, dose, and activity for the special unit equivalent "roentgen" (R).)
32. "Radiation exposure rate" means the radiation exposure per unit of time, such as R/min, mR/h, etc.
33. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.
34. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection requirements.
35. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.
36. "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.
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.
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.
39. "Regulations of the United States department of transportation" means the regulations in 49 CFR part 100-189.
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)).

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")
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.
43. "SI" means the abbreviation for the international system of units.
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).
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.
46. "Source material milling" means any activity that results in the production of byproduct material as defined in subdivision b of subsection 17.
47. "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
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.
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.
50. "These rules" means all parts of this article and any subsequent changes or additions thereto.
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.

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

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003; January 1, 2011.

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:

Mailing and shipping address:
North Dakota State Department of Health
Division of Air Quality
918 East Divide Avenue, Second Floor
Bismarck, ND 58501-1947

Telephone (701)328-5188
Facsimile (Fax) (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; January 1, 2011.

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

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

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

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

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

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

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

- a. One curie (Ci) = $3.7\text{E}+10$ disintegrations or transformations per second (dps or tps) = $3.7\text{E}+10$ becquerel (Bq) = $2.22\text{E}+12$ 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	nana	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