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Environmental Health Section

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June 19, 2002

U.S. Nuclear Regulatory Commission
Attn: Paul H. Lohaus, Director
Office of State and Tribal Programs
Mail Stop O-3-C-10
11555 Rockville Pike
Rockville, MD 20852

Dear Mr. Lohaus:

Enclosed for review and comment is a copy of the North Dakota Radiological Health Rules with proposed revisions. The amendment package is now out for public comment with final comments due September 16, 2002. The Department has also transmitted a copy of the proposed revisions to you via email.

The Department feels that adoption of these revisions will make the North Dakota Radiological Health Rules compatible with all applicable NRC rules, promulgated prior to and including the final rule for medical use of byproduct material issued April 24, 2002 (the enclosed table indicates which NRC rule makings were incorporated into this rule revision).

If you have any questions, please feel free to contact the Radiation Control Program at 701.328.5188, or send email to Ken Wangler, Radiation Control Program Manager at kwangler@state.nd.us.

Sincerely,

Terry O'Clair

Terry L. O'Clair, P.E.
Director
Division of Air Quality

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Enc:

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NRC RULES REVIEWED/INCORPORATED FOR PROPOSED REVISIONS (6/02)

DESCRIPTION	FR NOTICE (STATE DUE DATE)	RATS ID	10 CFR PART	ND CHAPTER 33-10-__
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction within an Agreement State.	62 FR 1662 (2/27/00)	1997-2	150	03
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations.	62 FR 28948 (6/27/00)	1997-5	30, 34, 71, 150	03, 05
Radiological Criteria for License Termination.	62 FR 39058 (8/20/00)	1997-6	20, 30, 40, 70	03, 04.1
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea.	62 FR 63634 (1/02/01)	1997-7	30	03
Deliberate Misconduct by Un-licensed Persons.	63 FR 1890 63 FR 13773 (2/12/01)	1998-1	30, 40, 61, 70, 150	03
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees.	63 FR 29535 (none)	1998-2	30, 40, 70	03
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.	63 FR 37059 (7/9/01)	1998-4	34	05
Minor Corrections, Clarifying Changes and a Minor Policy Change.	63 FR 39477 63 FR 45393 (10/26/01)	1998-5	20, 35, 36	04.1, 07.1, 14
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment.	63 FR 50127 (11/20/01)	1998-6	20	04.1
Radiological Criteria for License Termination of Uranium Recovery Facilities.	64 FR 17506 (6/11/02)	1999-1	40	03
Requirements for those who possess Certain Industrial Devices Containing Byproduct Material to Provide Information.	64 FR 42269 (none)	1999-2	31	03
Respiratory Protection and Controls to Restrict Internal Exposure.	64 FR 54543 64 FR 55525 (2/2/03)	1999-3	20	04.1
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications.	65 FR 20337 (5/17/03)	2000-1	39	12
New Dosimetry Technology.	65 FR 63749 (1/8/04)	2000-2	34, 36, 39	05, 12, 14
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material.	65 FR 79162 (2/16/04)	2001-1	30, 31, 32	03
Revision of the Skin Dose Limit.	67 FR 16298 (6/4/05)		20	01, 04.1
Medical Use of Byproduct Material - Final Rule.	65 FR 20250 (10/24/05)		20, 32, 35	03, 04.1, 07.1

CHAPTER 33-10-01
GENERAL PROVISIONS

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

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

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

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

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

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

8. "Agreement state" means any state with which the United States nuclear regulatory commission has entered into an effective

agreement under section 274(b) of the Atomic Energy Act of 1954, as amended [73 Stat. 688; 42 U.S.C. 2021].

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

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

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

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

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

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

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

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

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

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

17. "Byproduct material" means:

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

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

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

19. "Calibration" means the determination of:

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

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

20. "CFR" means Code of Federal Regulations.

21. "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids, 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. "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. "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. "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. "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. "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. "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. "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of three tenths centimeter (or a density thickness of 300 mg/cm²). This assumes a tissue density of one gram per cubic centimeter.~~

~~43~~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.

~~44~~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.

~~45~~44. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram [100 rad].

~~46~~45. "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.

~~47~~46. "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.

~~48~~47. "High radiation area" means any area, accessible to individuals, in which radiation levels <u>from radiation sources external to the body</u> 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.

~~49~~48. "Human use" means the internal or external administration of radiation or radioactive material to human beings.

~~50~~49. "Individual" means any human being.

~~51~~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).

~~52~~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, ~~thermoluminescent~~ thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

~~53~~52. "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.

~~54~~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.

~~55~~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. "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. "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. "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. "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.

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. "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. "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. "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 sources of radiation, whether or not the sources are in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with ~~subsection 12 of section 33-10-07-05~~ 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. "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 ~~this state to compound and dispense drugs, prescriptions, and poisons~~ a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

80. "Physician" means ~~an individual licensed by this state to dispense drugs in the practice of medicine~~ 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. "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

~~82~~83. "Public dose" means the dose received by a member of the public from sources of radiation from a licensed or registered operation. 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 ~~subsection 12 of section 33-10-07-05~~ 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.

~~83~~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.

~~84~~85. "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.

~~85~~86. "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).

~~86~~87. "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.

~~87~~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.

~~88~~89. "Radiation dose" (see "dose").

~~89~~90. "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).)

~~90~~91. "Radiation exposure rate" means the radiation exposure per unit of time, such as R/min, mR/h, etc.

~~91~~92. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

~~92~~93. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

~~93~~94. "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.

~~94~~95. "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

~~95~~96. "Radiobioassay" (see "bioassay").

~~96~~97. "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.

~~97~~98. "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.

~~98~~99. "Regulations of the United States department of transportation" means the regulations in 49 CFR, 100-189.

~~99~~100. "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)).

~~100~~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.

~~101~~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.

~~102~~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.

~~103~~104. "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").

~~104~~105. "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.

~~105~~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, ~~means~~ is taken as the dose equivalent at a tissue depth of seven one-thousandths centimeter [7 mg/cm^2] ~~averaged over an area of one square centimeter~~.

~~106~~107. "SI" means the abbreviation for the international system of units.

~~107~~108. "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).

~~108~~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.

~~109~~110. "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

~~110~~111. "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.

~~111~~112. "Source material milling" means any activity that results in the production of byproduct material as defined in subdivision b of subsection 17.

~~112~~113. "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~113~~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.

~~114~~115. "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.

~~115~~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:

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

~~116~~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.

~~117~~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.

~~118~~119. "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.

~~119~~120. "These rules" means all parts of this article and any subsequent changes or additions thereto.

~~120~~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.

~~121~~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.

~~122~~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).

~~123~~124. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

~~124~~125. "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

~~125~~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.

~~126~~127. "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.

~~127~~129. "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

~~128~~130. "Week" means seven consecutive days starting on Sunday.

~~129~~131. "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

~~130~~132. "Worker" means an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant.

~~131~~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.

~~132~~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.

~~133~~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.
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 ~~Environmental Engineering~~ Air Quality
1200 Missouri Avenue, Room 304
~~Box 5520~~
Bismarck, North Dakota ~~58506-5520~~ 58504

Mailing
North Dakota Department of Health
Division of Air Quality
Box 5520
Bismarck, ND 58506-5520

Telephone (701)328-5188
Facsimile (FAX) (701)328-5200
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.
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

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

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

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

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

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

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

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

Table III
SI Numerical Prefix Conversion Table

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

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

CHAPTER 33-10-03
LICENSING OF RADIOACTIVE MATERIAL

Section	
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33-10-03-04	General Licenses
33-10-03-05	Specific Licenses
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33-10-03-01. Purpose and scope.

1. This chapter and chapters 33-10-07 and 33-10-13 provide for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized pursuant to this chapter or chapters 33-10-07 and 33-10-13, or as otherwise provided in these chapters.

2. In addition to the requirements of this chapter, all licensees are subject to the requirements of chapters 33-10-01, 33-10-04.1, 33-10-10, 33-10-11 and 33-10-13. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of chapter 33-10-05, licensees using radionuclides in the healing arts are subject to the requirements of chapter 33-10-07.1, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of chapter 33-10-12.

History: Amended Effective June 2, 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

33-10-03-02. Exemptions.

1. **Source material.**

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

twentieth of one percent of the mixture, compound, solution, or alloy.

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

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

(1) Any quantities of thorium contained in:

(a) Incandescent gas mantles.

(b) Vacuum tubes.

(c) Welding rods.

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

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

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

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

(2) Source material contained in the following products:

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

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

(c) Glass enamel or glass enamel frit containing not more than ten percent by weight source material

imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Exempt concentrations.

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

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

b. Exempt quantities.

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

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

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this subdivision or equivalent regulations of the United States nuclear regulatory commission, any agreement state, or a licensing state, except in accordance with a specific license issued by the United States nuclear regulatory commission pursuant to 10 CFR 32.18 or by the department pursuant to subdivision b of subsection 5 of section 33-10-03-05 which license states that the radioactive material may be transferred by the licensee to persons exempt under this subdivision or the equivalent regulations of the United States nuclear regulatory commission, any agreement state or a licensing state.

c. Exempt items.

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

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

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

[2] One hundred eighty five megabecquerels [5 millicuries] of tritium per hand.

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

[4] Three and seven tenths megabecquerels [100 microcuries] of promethium-147 per watch or seven and four tenths megabecquerels [200 microcuries] of promethium-147 per any other timepiece.

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

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

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

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

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

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

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

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

(c) Balances of precision containing not more than thirty-seven megabecquerels [1 millicurie] of tritium per balance or not more than eighteen and a half megabecquerels [0.5 millicurie] of tritium per balance part.

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

(e) Marine compasses containing not more than twenty-seven and seventy-five hundredths gigabecquerels [750 millicuries] of tritium gas and other marine navigational instruments containing not more than nine and twenty-five hundredths gigabecquerels [250 millicuries] of tritium gas.

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

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

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

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

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

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

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

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

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

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

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

[2] Each instrument contains no more than 10 exempt quantities. For purposes of this subparagraph an instrument's source may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

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

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

(2) Self-luminous products containing radioactive material.

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

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

(3) Gas and aerosol detectors containing radioactive material.

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

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

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

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic

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

(5) Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

(a) Except as provided in subparagraphs (b) and (c) of this paragraph, any person is exempt from the requirements of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kilobecquerels (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to chapter 33-10-07.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to section 33-10-03-05 of this chapter.

(d) Nothing in this paragraph relieves persons from complying with applicable United States food and drug administration, other federal, and state requirements governing receipt, administration, and use of drugs.

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

33-10-03-03. Licenses. Licenses for radioactive materials are of two types: general and specific.

1. General licenses provided in this chapter are effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although registration with the department or the filing of a certificate with the department may be required by the particular general license. The general licensee is subject to all other applicable portions of this article and any limitations of the general license.

2. Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of this article as well as any limitations specified in the licensing document.

History: Amended effective June 1, 1992.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04, 23-20.1-03

33-10-03-04. General licenses.

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

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

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

   c. Persons who receive, possess, use, or transfer source material pursuant to the general license in subdivision a are

prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the department in a specific license.

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

e. Depleted uranium in industrial products and devices.

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

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

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

[1] Name and address of the registrant.

[2] A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in paragraph 1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons

not authorized to receive the depleted uranium.

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

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

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

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

(b) May not abandon such depleted uranium.

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

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

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

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

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

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

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

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

b. Certain detecting, measuring, gauging, ~~and~~ or controlling devices and certain devices for producing light or an ionized atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use, or transfer in accordance with the provisions of paragraphs 2, 3, and 4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

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

<u>The devices must have been received from one of the specific licensees described in paragraph 2 or through a transfer made under subparagraph i of paragraph 3.</u>

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

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

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

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

[2] Devices containing only tritium or not more than three and seven tenths megabecquerels [100 microcuries] of other beta or gamma emitting material or thirty-seven hundredths megabecquerels [10 microcuries] of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

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

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

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

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

(e) ~~Upon the occurrence of~~ Shall immediately suspend operation of the device if there is a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of one hundred eighty-five becquerels [0.005 microcurie] or more removable radioactive material. ~~, shall immediately suspend operation of the device~~ The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license from the department, the United States nuclear regulatory commission, an agreement state or a licensing state to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device or as otherwise approved by the department. ~~and, within thirty days, furnish to the department a~~ A report containing a brief description of the event and the remedial action taken; and in the case of detection of one hundred eighty-five becquerels [0.005 microcurie] or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the department within thirty days. Under these circumstances, the criteria set out in subsection 2 ("radiological criteria for unrestricted use") of section 33-10-04.1-18 may be applicable, as determined by the department on a case-by-case basis.

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

(g) Shall not export the device containing radioactive material except in accordance with 10 CFR part 110.

~~(g) Except as provided in subparagraph h, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the United States nuclear regulatory commission, an agreement state or a licensing state whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by~~

~~manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device.~~

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

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

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

~~(i) Shall comply with the provisions of subsections 1, 2, 3, and 5 of section 33-10-04.1-16 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of chapter 33-10-04.1 and 33-10-10.~~

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

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

(h) [1] Shall transfer or dispose of the device containing radioactive material only by export as provided by 10 CFR part 110, by transfer to another general licensee as authorized in subparagraph i, or to a person authorized to receive the device by a specific license issued under this chapter (including licenses under this chapter authorizing waste collection), or equivalent regulations of the United States nuclear regulatory commission,

an agreement state, a licensing state, or as otherwise approved under item 3.

[2] Shall furnish a report to the department within thirty days after the transfer of a device to a specific licensee or export. The report must contain--

[a] The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

[b] The name, address, and license number of the person receiving the device (license number not applicable if exported); and

[c] The date of the transfer.

[3] Shall obtain written department approval before transferring the device to any other specific licensee not specifically identified in item 1.

(i) Shall transfer the device to another general licensee only if--

[1] The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this subdivision, section 33-10-03-01, subsection 4 of section 33-10-03-04, section 33-10-03-10, and subsections 1 and 2 of section 33-10-04.1-16, and any safety documents identified in the label of the device. Within thirty days of the transfer, the transferor shall report to the department--

[a] The manufacturer's (or initial transferor's) name;

[b] The model number and the serial number of the device transferred;

[c] The transferee's name and mailing address for the location of use; and

[d] The name, title, and phone number of the responsible individual identified by the transferee in accordance with subparagraph 1 to have knowledge of and authority to take actions to ensure

compliance with the appropriate rules and requirements; or

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

(j) Shall comply with the provisions of subsections 1 and 2 of section 33-10-04.1-16 for reporting radiation incidents, and theft or loss of licensed material, but shall be exempt from the other requirements of chapters 33-10-04.1 and 33-10-10.

(k) Shall respond to written requests from the department to provide information relating to the general license within thirty calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the department and provide written justification as to why it cannot comply.

(l) Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(m) [1] Shall register, in accordance with items 2 and 3, devices containing at least three hundred seventy megabecquerels [ten millicuries] of cesium-137, three thousand seven hundred kilobecquerels [one hundred microcuries] of strontium-90, thirty seven megabecquerels [one millicurie] of cobalt-60, or thirty seven megabecquerels [one millicurie] of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (ninety two)), based on the activity indicated on the label. Each address for a location of use, as described under subitem d of item 3, represents a separate general licensee and requires a separate registration and fee.

[2] If in possession of a device meeting the criteria of item 1, shall register these devices annually with the department and shall pay the fee required by chapter 33-10-11. Registration must be done by verifying, correcting, and adding to the information provided in a request for registration received from the department. The registration information must be submitted to the department within thirty days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of item 1 is subject to the bankruptcy notification requirement in subsection 3 of section 33-10-03-04.

[3] In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the department--

[a] Name and mailing address of the general licensee.

[b] Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

[c] Name, title, and telephone number of the responsible person designated as a representative of the general licensee under subparagraph 1.

[d] Address or location at which the device(s) are used and stored. For portable devices, the address of the primary place of storage.

[e] Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

[f] Certification by the responsible representative of the general licensee

that they are aware of the requirements of the general license.

[4] Persons generally licensed by another agreement state or licensing state or the United States nuclear regulatory commission with respect to devices meeting the criteria in item 1 of subparagraph m are not subject to registration requirements if the devices are used in areas subject to department jurisdiction for a period less than one hundred eighty days in any calendar year. The department will not request registration information from such licensees.

(n) Shall report changes to the mailing address for the location of use (including change in the name of the general licensee) to the department within thirty days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(o) May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by subparagraph b of paragraph 3 need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

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

(5) General license to install devices generally licensed in subdivision b. Any person who holds a specific license issued by the United States nuclear regulatory commission or an agreement state or a licensing state authorizing the holder to manufacture, install, or service a device described in subdivision b within an agreement state or licensing state or non-agreement state is hereby granted

a general license to install and service such device in areas subject to department jurisdiction, provided that:

(a) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the United States nuclear regulatory commission or the agreement state or the licensing state.

(b) Such person assures that any labels required to be affixed to the device under rules or regulations of the United States nuclear regulatory commission or the agreement state or the licensing state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

c. Luminous safety devices for aircraft.

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

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

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

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

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

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

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

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

e. Calibration and reference sources.

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

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

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

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

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

which authorizes the person to receive, possess, use, and transfer radioactive material.

(4) The general licenses in paragraphs 1, 2, and 3 apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States nuclear regulatory commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39 of the regulations of the United States nuclear regulatory commission.

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

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

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

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

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

_____
(name of manufacturer or importer)

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

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

_____
(name of manufacturer or importer)

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

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

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

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

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

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of

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

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

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

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

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

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

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

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

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

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

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

(b) The location of use.

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

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

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

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

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

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

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

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

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

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

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

_____

(name of manufacturer)

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

_____

(name of manufacturer)

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

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

g. Ice detection devices.

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

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph 1:

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

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

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

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

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

3. **Bankruptcy.** Each general licensee that is required to register by subparagraph m of paragraph 3 of subdivision b of subsection 2 of section 33-10-03-04 and each specific licensee shall notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (bankruptcy) of the United States Code by or against:

a. The licensee;

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

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

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

4. **Terms and conditions.** The general licenses provided in this section are subject to the requirements listed in section 33-10-03-01, including subsections 6, 7, 12, and 13 of section 33-10-03-05, unless indicated otherwise in the specific provision of the general license.

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

33-10-03-05. Specific licenses.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

g. Financial surety arrangements for site reclamation.

(1) Pursuant to North Dakota Century Code section 23-20.1-04.2 and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in paragraph 3 shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the North Dakota Century Code and this article.

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

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

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

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

(a) Major processors.

(b) Waste handling licensees.

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

(d) Source material milling operations.

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

(4) For source material milling operations, the amount of funds to be ensured by such surety arrangements shall be based on department-approved cost estimates in an approved plan for (a) decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and (b) the reclamation of tailings or waste disposal areas in accordance with the technical criteria delineated in chapter 33-10-03. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. In addition, the surety shall cover the payment of the charge for long-term surveillance and control required by the department. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the

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

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

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

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

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

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

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

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

(1) Waste handling licensees.

(2) Source material milling licensees.

i. Continued surveillance requirements for source material mills.

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

(2) A minimum charge of ~~two~~ six hundred ~~fifty~~ eighty thousand dollars (~~1978~~ 2001 dollars) to cover the costs of long-term surveillance shall be paid by each mill operator to the department prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in paragraph 1, e.g., if fencing is determined to be necessary, variance in funding requirements may be specified by the department. The total charge to cover the costs of long-term surveillance shall be such that, with an assumed one percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The charge will be adjusted annually prior to actual payments to recognize inflation. The inflation rate to be used is that indicated by the change in the consumer price index published by the United States department of labor, bureau of labor statistics.

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

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

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

(a) Initial training.

(b) Periodic training.

(c) On-the-job training.

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

(2) The applicant has established and submits to the department satisfactory written operating and emergency procedures described in subsection ~~2~~ 4 of section 33-10-05-~~06~~ 05.

(3) The applicant will have an internal inspection system adequate to assure that this article, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system must include the performance of internal inspections at intervals not to exceed ~~three~~ six months and the retention of records of such inspections for ~~two~~ three years.

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

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

(a) Instrumentation to be used.

(b) Method of performing tests.

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

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

(7) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(8) The applicant identifies and lists the qualifications of the individual(s) designated as the radiation safety officer (RSO) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the

procedures described and at the intervals not to exceed six months and after servicing.

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by this chapter and other chapters of this article will be maintained.

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

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

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

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

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

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

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

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

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

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

(g) Other factors appropriate for the specific facility.

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

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

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

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

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

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

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

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

(h) Notification and coordination. A commitment to a brief description of the means to promptly notify

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

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

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

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

(l) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios

postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

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

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

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

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

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

(2) A "type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Schedule C, for

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

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

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

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

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

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

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

(b) The appointment of a radiation safety officer who is qualified by training and experience in

radiation protection, and who is available for advice and assistance on radiation safety matters.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial

concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer.

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

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

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

(1) An application for a specific license to distribute naturally occurring and accelerator-produced radioactive

material to persons exempted from this article pursuant to subdivision b of subsection 2 of section 33-10-03-02 will be approved if all of the following are met:

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

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

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

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

(a) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

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

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

(d) In addition to the labeling information required by subparagraph c, the label affixed to the immediate

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

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

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

d. ~~Licensing the manufacture and distribution of devices to persons generally licensed~~ Radioactive material contained in devices for use under subdivision b of subsection 2 of section 33-10-03-04. Requirements for license to manufacture, or initially transfer. Conditions of licenses. Material transfer reports and records.

(1) An application for a specific license to manufacture or ~~distribute~~ initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory

commission, an agreement state, or a licensing state will be approved if:

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

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

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

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

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

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

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

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

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

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

[a] The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the rules of the United States nuclear regulatory commission or a state with which the U.S. nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. (The model, serial number, and name of manufacturer or ~~distributor~~ initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.) This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

(name of manufacturer or ~~distributor~~ initial transferor)

[b] The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a

general license or the equivalent and the regulations of a licensing state. (The model, serial number, and name of manufacturer or ~~distributor~~ initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.) This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

(name of manufacturer or ~~distributor~~ initial transferor)

(d) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in subsection 1 of section 33-10-04.1-13, and the name of the manufacturer or initial distributor.

(e) Each device meeting the criteria of item 1 of subparagraph m of paragraph 3 of subdivision b of subsection 2 of section 33-10-03-04 bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in subsection 1 of section 33-10-04.1-13.

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

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

(a) Primary containment or source capsule.

(b) Protection of primary containment.

(c) Method of sealing containment.

(d) Containment construction materials.

(e) Form of contained radioactive material.

(f) Maximum temperature withstood during prototype tests.

(g) Maximum pressure withstood during prototype tests.

(h) Maximum quantity of contained radioactive material.

(i) Radiotoxicity of contained radioactive material.

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

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

(4) Conditions of licenses.

(a) If a device containing radioactive material is to be transferred for use under the general license contained in subdivision b of subsection 2 of

section 33-10-03-04, each person that is licensed under subdivision d of subsection 5 of section 33-10-03-05 shall provide the information specified in this subparagraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

[1] A copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04. If subparagraphs b, c, d, or m of paragraph 3 of subdivision b do not apply to the particular device, those paragraphs may be omitted.

[2] A copy of subsection 4 of section 33-10-03-04, section 33-10-03-10, and subsections 1 and 2 of section 33-10-04.1-16.

[3] A list of the services that can only be performed by a specific licensee.

[4] Information on acceptable disposal options including estimated costs of disposal.

[5] An indication that the department's policy is to issue high civil penalties for improper disposal.

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of the United States nuclear regulatory commission, an agreement state, or a licensing state, each person that is licensed under subdivision d of subsection 5 of section 33-10-03-05 shall provide the information specified in this subparagraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

[1] A copy of the United States nuclear regulatory commission's, agreement state's, or licensing state's rules equivalent to subdivision b of

subsection 2 of section 33-10-03-04, subsection 4 of section 33-10-03-04, section 33-10-03-10, and subsections 1 and 2 of section 33-10-04.1-16. If a copy of the North Dakota rules is provided to a prospective general licensee in lieu of the equivalent rules of the United States nuclear regulatory commission, agreement state, or licensing state, it shall be accompanied by a note explaining that use of the device is regulated by the United States nuclear regulatory commission, agreement state, or licensing state (whichever is correct). If certain paragraphs of the rules do not apply to the particular device, those paragraphs may be omitted.

[2] A list of the services that can only be performed by a specific licensee.

[3] Information on acceptable disposal options including estimated costs of disposal.

[4] The name or title, address, and phone number of the contact at the United States nuclear regulatory commission, agreement state, or licensing state regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the department.

(d) Each device that is transferred must meet the labeling requirements in subparagraphs c through e of paragraph 1 of subdivision d of subsection 5 of section 33-10-03-05.

(e) If a notification of bankruptcy has been made under subsection 3 of section 33-10-03-04 or subsection 7 of section 33-10-03-05 or the license is to be terminated, each person licensed under subdivision d of subsection 5 of section 33-10-03-05 shall provide, upon request, to the department, the United States nuclear regulatory commission, and to any appropriate agreement state or licensing state, records of final disposition required under subparagraph c of paragraph 5 of subdivision d of subsection 5 of section 33-10-03-05.

(5) Material transfer reports and records. Each person licensed under subdivision d of subsection 5 of section 33-10-03-05 to initially transfer devices to generally licensed persons shall comply with the requirements of this paragraph.

(a) The person shall report all transfers of devices to persons for use under the general license in subdivision b of subsection 2 of section 33-10-03-04 and all receipts of devices from persons licensed under subdivision b of subsection 2 of section 33-10-03-04 to the department. The report must be submitted on a quarterly basis on United States nuclear regulatory commission form 653 "transfers of industrial devices report" or in a clear and legible report containing all of the data required by the form.

[1] The required information for transfers to general licensees includes--

[a] The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

[b] The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

[c] The date of transfer;

[d] The type, model number, and serial number of the device transferred; and

[e] The quantity and type of radioactive material contained in the device.

[2] If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

[3] For devices received from a general licensee under subdivision b of subsection 2 of section 33-10-03-04, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

[4] If the licensee makes changes to a device possessed by a general licensee under subdivision b of subsection 2 of section 33-10-03-04, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

[5] The report must cover each calendar quarter, must be filed within thirty days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

[6] The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

[7] If no transfers have been made to or from persons generally licensed under subdivision b of subsection 2 of section 33-10-03-04 during the reporting period, the report must so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license in the United States nuclear regulatory commission's regulations, agreement state's regulations, or licensing state's regulations that are equivalent to subdivision b of subsection 2 of section 33-10-03-04; and all receipts of devices from general licensees in the United States nuclear regulatory commission's, agreement state's, or licensing state's jurisdiction to the responsible agency. The report must be submitted on form 653 "transfers of industrial devices report" or in a clear and legible report containing all of the data required by the form.

[1] The required information for transfers to general licensees includes--

[a] The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

[b] The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

[c] The date of transfer;

[d] The type, model number, and serial number of the device transferred; and

[e] The quantity and type of radioactive material contained in the device.

[2] If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

[3] For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

[4] If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

[5] The report must cover each calendar quarter, must be filed within thirty days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

[6] The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

[7] If no transfers have been made to or from a particular agreement state, licensing state, or United States nuclear regulatory commission state during the reporting period, this information shall be reported to the responsible agency upon request of the agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by paragraph 5, "material transfer reports and records." Records required by this subparagraph must be maintained for a period of three years following the date of the recorded event.

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

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

~~(b) Furnish a copy of the general license contained in the United States nuclear regulatory commission's, agreement state's, or licensing state's regulation equivalent to subdivision b of subsection 2 of section 33-10-03-04, or alternatively, furnish a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04 to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the United States nuclear regulatory commission, the agreement state, or the licensing state. If a copy of the general license~~

~~in subdivision b of subsection 2 of section 33-10-03-04 is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the United States nuclear regulatory commission, agreement state, or licensing state under requirements substantially the same as those in subdivision b of subsection 2 of section 33-10-03-04.~~

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

~~(d) Furnish reports to other agencies.~~

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

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

~~[3] Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general~~

~~licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within thirty days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Mock iodine-125 in units not exceeding one and eighty-five hundredths kilobecquerels [0.05 microcurie] of iodine-129 and one and eighty-five hundredths kilobecquerels [0.05 microcurie] of americium-241 each.

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

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

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

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

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed three hundred seventy kilobecquerels [10 microcuries] of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; one and eighty-five hundredths megabecquerels [50 microcuries] of hydrogen-3 (tritium); seven hundred forty kilobecquerels [20 microcuries] of iron-59; or mock iodine-125 in units not exceeding one and eighty-five hundredths kilobecquerels [0.05 microcurie] of iodine-129 and one hundred eighty-five hundredths becquerels [0.005 microcurie] of americium-241 each.

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

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

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

_____

(name of manufacturer)

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

_____

(name of manufacturer)

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

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

i. Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 33-10-07.1.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution of radioactive drugs containing radioactive material for use by persons ~~licensed pursuant to this chapter for the uses listed in subsection 1 of section 33-10-07-06, subsection 1 of section 33-10-07-07, or subsection 1 of section 33-10-07-08~~ authorized pursuant to chapter 33-10-07.1 will be approved if:

(a) The applicant satisfies the general requirements specified in subsection 2 of section 33-10-03-05.

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

[1] Registered or licensed with the United States food and drug administration as a drug manufacturer;

[2] Registered or licensed with a state agency as a drug manufacturer;

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

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

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

(d) The applicant satisfied the following labeling requirements:

[1] A label is affixed to each transport radiation shield whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than ~~100~~ one hundred days, the time may be omitted.

[2] A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

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

(a) May prepare radioactive drugs for medical use, as defined in section 33-10-07~~-01.1~~ .1-02, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in subparagraphs ~~2~~ b and ~~3~~ d, or an individual under the supervision of an authorized nuclear pharmacist as specified in ~~subsection 5 of~~ section 33-10-07~~-04~~ .1-16.

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

[1] This individual qualifies as an authorized nuclear pharmacist as defined in section 33-10-07~~-01~~.1-02,

[2] This individual meets the requirements specified in ~~subsection 13 of section 33-10-07-12 and subdivision b of subsection 15 of section 33-10-07-12~~ section 33-10-07.1-24 and subsection 2 of section 33-10-07.1-22 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

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

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

(d) May designate a pharmacist (as defined in section 33-10-07~~-01~~.1-02) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the United State nuclear regulatory commission under 10 Code of Federal Regulations part 32.

(e) Shall provide to the department a copy of each individual's certification by the board of pharmaceutical specialties, the United States nuclear regulatory commission or agreement state or licensing state license, or the permit issued by a licensee of broad scope, and a copy of the state

pharmacy licensure or registration no later than ~~30~~ thirty days after the date that the licensee allows; pursuant to items 1 and 3 of subparagraph ~~3~~ b, the individual to work as an authorized nuclear pharmacist.

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

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

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

(4) Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kilobecquerels (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use, to persons exempt from licensing under section 33-10-03-02 or the equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:

[1] The applicant satisfies the general requirements specified in subsection 33-10-03-05.2, provided that the requirements of 33-10-03-05.2.a and c of this subsection do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or

repackaged pursuant to a license issued by an agreement state;

[2] The applicant meets the requirements under subdivision 33-10-03-05.2.b of this chapter;

[3] The applicant provides evidence that each capsule contains 37 kilobecquerels (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

[4] The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this subdivision) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

[5] The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

[6] The applicant submits copies of prototype labels and brochures and the department or United States nuclear regulatory commission approves these labels and brochures.

(b) Conditions of license. Each license issued under 33-10-03-05.5.i of this chapter is subject to the following conditions: [1] The immediate container of the capsule(s) must bear a durable, legible label which: [a] Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and [b] Bears the words "Radioactive Material." [2] In addition to the labeling information required by item [1] of this subparagraph, the label affixed to the immediate container, or an accompanying brochure also must: [a] State that the contents are exempt from United States nuclear regulatory commission or agreement state licensing requirements; and [b] Bears the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, Other Drugs or Medicinals, or into Products Manufactured for

Commercial Distribution. This Material May Be Disposed of in Ordinary Trash."

~~(4)~~(5) Nothing in this subdivision relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs.

j. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to chapter 33-10-07.1 for use as a calibration or reference source or for the uses listed in ~~subsection 1 of section 33-10-07-09 and subsection 1 of section 33-10-07-10~~ section 33-10-07.1-47, section 33-10-07.1-57, and section 33-10-07.1-59 will be approved if:

(1) The applicant satisfies the general requirements in subsection 2 or section 33-10-03-05.

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

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

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

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

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

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

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

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

(h) Instructions for handling and storing the source or device from the radiation safety standpoint; these

instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the ~~source or device is licensed by the department for distribution to persons licensed pursuant to chapter 33-10-07, subsection 1 of section 33-10-07-09, and subsection 1 of section 33-10-07-10, or under equivalent licenses of the United States nuclear regulatory commission, an agreement state, or a licensing state, provided, that such labeling for sources which do not require long-term storage may be on a leaflet or brochure which accompanies the source~~ department has approved distribution of the (name or source or device) to persons licensed to use radioactive material identified in sections 33-10-07.1-28, 33-10-07.1-47, 33-10-07.1-57 and 33-10-07.1-59, as appropriate, and to persons who hold an equivalent license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state.

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

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

(a) Primary containment or source capsule.

(b) Protection of primary containment.

(c) Method of sealing containment.

(d) Containment construction materials.

(e) Form of contained radioactive materials.

(f) Maximum temperature withstood during prototype tests.

(g) Maximum pressure withstood during prototype tests.

(h) Maximum quantity of contained radioactive material.

(i) Radiotoxicity of contained radioactive material.

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

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

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

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar year a radiation dose in excess of ten percent of the limits specified in subsection 1 of section 33-10-04.1-06.

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

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

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

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

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

(b) Label or mark each unit to:

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

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

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium".

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

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

(e) Report to the department all transfers of industrial products or devices to persons for use under the general license in subdivision e of subsection 1 of section 33-10-03-04. Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under subdivision e of subsection 1 of section 33-10-03-04 during the reporting period, the report shall so indicate.

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

[2] Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to this subdivision for use under a general license in that state's

regulations equivalent to subdivision e of subsection 1 of section 33-10-03-04.

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

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

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

(g) Keep records showing the name, address, and point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in subdivision e of subsection 1 of section 33-10-03-04 or equivalent regulations of the United States nuclear regulatory commission or of an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this subsection.

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

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

(a) Description of the proposed project or action.

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

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

(d) Environmental effects of accidents.

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

(f) Site and project alternatives.

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

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

(3) At least one full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

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

(a) The amount of funds to be ensured by financial surety arrangements shall be based on department-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee shall submit this plan in conjunction with an

environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the department may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the department to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time, e.g., five years, which must be automatically renewed unless the surety agent notifies the beneficiary (the state regulatory agency) and the principal (the licensee) some reasonable time, e.g., ninety days, prior to the

renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least sixty days for the regulatory agency to collect.

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

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

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

(b) The mill operator shall conduct daily inspection of any tailings or waste retention systems. Records of such inspections shall be maintained for review by the department.

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

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

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

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

(a) The final disposition of tailings or wastes at source material milling sites should be such that

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

(b) A minimum charge of ~~two~~ six hundred ~~fifty~~ eighty thousand dollars in ~~1978~~ 2001 dollars to cover the costs of long-term surveillance shall be paid by each mill operator to the department prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in subparagraph a, additional funding requirements may be specified by the department. The total charge to cover the costs of long-term surveillance shall be such that, with an assumed one percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The charge will be reviewed annually to recognize or adjust for inflation.

(7) An application for a license to ~~own,~~ receive, possess and use source material for uranium or thorium milling or byproduct material, as defined in section 33-10-01-04, at sites formerly associated with such milling shall contain proposed written specifications relating to milling operations and the ~~emissions control and~~ disposition of the byproduct material to achieve the requirements and objectives set forth ~~in the criteria listed~~ in Schedule D of chapter 33-10-03. Each application must clearly demonstrate how the requirements and objectives set forth in Schedule D of chapter 33-10-03 have been addressed. Failure to clearly demonstrate how the requirements and objectives in Schedule D have been addressed shall be grounds for refusing to accept an application.

6. **Issuance of specific licenses.**

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

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

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

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

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

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

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

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information find that the transfer is in accordance with the provisions of North Dakota Century Code chapter 23-20.1, now or hereafter in effect, and to all valid rules and orders of the department, and shall give its consent in writing.

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

d. Licensees required to submit emergency plans under subdivision b of subsection 3 shall follow the emergency plan approved by the department. The licensee may change the ~~proved~~ approved plan without department approval only if the changes do not

decrease the effectiveness of the plan. The licensee shall furnish the change to the department and to affected onsite response organizations within six months after the change is made. Proposed changes that decrease or potentially decrease the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the department.

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

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

(1) The licensee;

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

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

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

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

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

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

stated in the determination, or as otherwise provided by department order.

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

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

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

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

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

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

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

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

e. Coincident with the notification required by subdivision d, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to subsection 14 in conjunction with a license issuance or renewal or as required by this subsection. The amount of the

financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subparagraph e of paragraph 4 of subdivision g.

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

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

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

g. (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

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

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

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

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

(2) The department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to

subdivision d if the department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

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

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

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

(b) A description of planned decommissioning activities;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Radioactive material has been properly disposed;

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

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

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

(4) Records required by ~~subsection 14 of section 33-10-03-05 and sections 14 and 15 of chapter 33-10-04.1~~ subsections 4 and 6 of section 33-10-03-10 have been received.

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

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

11. **Department action on applications to renew or amend.** In considering an application by a licensee to renew or amend the license, the department will apply the criteria set forth in

subsection 2, 3, 4, 5, or 14, and chapters 33-10-05, 33-10-07, or 33-10-12, as applicable.

12. **Transfer of material.**

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

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

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

(2) To the United States department of energy.

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

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States nuclear regulatory commission, any agreement state, or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the department, an agreement state, or a licensing state.

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

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

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

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

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

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

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

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

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

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

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

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

an original application, or for violation of, or failure to observe any of the terms and conditions of North Dakota Century Code chapter 23-20.1, or of the license, or of this article, or order of the department.

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

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

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than one hundred twenty days and in quantities exceeding one hundred thousand times the applicable quantities set forth in Schedule F of this chapter shall submit a decommissioning funding plan as described in subdivision e. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by one hundred thousand is greater than one (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in schedule F of this chapter.

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

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

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

certification, a signed original of the financial instrument obtained to satisfy the requirements of subdivision f.

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

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

(3) Each holder of a specific license of a type described in subdivision b shall submit a decommissioning funding plan as described in subdivision e or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this subsection.

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

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

Greater than ten billion times the applicable quantities of Schedule F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in subdivision a, divided by ten billion is greater than one) $75,000

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

f. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Schedule G. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subsection. ~~A~~ For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in schedule H. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in schedule I. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the

applicant or licensee may be used if the guarantee and test are as contained in schedule J. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this subsection or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(a) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless ninety days or more prior to the renewal date, the issuer notifies the department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the department within thirty days after receipt of notification of cancellation.

(b) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the department. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(c) The surety method or insurance must remain in effect until the department has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or

insurance provisions must be as stated in paragraph 2 of subdivision f.

(4) In the case of state or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in subdivision d, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental ~~agency~~ entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental ~~agency~~ entity.

g. Each person licensed shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with subdivision b of subsection 7 of section 33-10-03-05, licensees shall transfer all records described in this subdivision to the new licensee. In this case, the new licensee shall maintain these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the department considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains

after any leak) or radioactive materials having only half-lives of less than sixty-five days, a list contained in a single document and updated every two years, of the following:

(a) All areas designated and formerly designated as restricted areas as defined in section 33-10-01-04;

(b) All areas outside of restricted areas that require documentation under paragraph 1 of subdivision g;

(c) All areas outside of restricted areas where current and previous wastes have been buried as documented under subsection 9 of section 33-10-04.1-15; and

(d) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in section ~~18 of chapter 33-10-04.1~~ 33-10-04.1-18 or apply for approval for disposal under subsection 2 of section 33-10-04.1-14.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

History: Amended effective October 1, 1982, June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998.
General Authority: NDCC 23-20.1-04, 23-20.1-04.1, 23-20.1-04.2, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.1, 23-20.1-04.2, 23-20.1-04.5

33-10-03-06. Reciprocal recognition of licenses.

1. Licenses of byproduct, source, and special nuclear material in quantities not sufficient to form a critical mass.

   a. Subject to this article, any person who holds a specific license from the United States nuclear regulatory commission or an agreement state and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state except in areas of exclusive federal jurisdiction for a period not in excess of one hundred

eighty days in ~~any calendar year~~ the three hundred sixty-five day period the reciprocity agreement is active provided that:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations.

(2) The out-of-state licensee notifies the department in writing, for each occurrence, at least three working days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document and a copy of the licensee's operating and procedures manual. If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the ~~calendar year~~ three hundred sixty-five day period the reciprocity agreement is active following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

(3) The out-of-state licensee complies with this article and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with this article.

(4) The out-of-state licensee supplies such other information as the department may request.

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subdivision except by transfer to a person:

(a) Specifically licensed by the department or the United States nuclear regulatory commission to receive such material; or

(b) Exempt from the requirements for a license for such material under subdivision a of subsection 2 of section 33-10-03-02.

(6) The out-of-state licensee shall submit an annual reciprocity fee, as prescribed in chapter 33-10-11, at the time of ~~written notification~~ initial request for reciprocity.

b. Notwithstanding the provisions of subdivision a, any person who holds a specific license issued by the United States nuclear regulatory commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in paragraph 1 of subdivision b of subsection 2 of section 33-10-03-04 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state <u>except in areas of federal jurisdiction</u> provided that:

(1) The person shall file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device.

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the United States nuclear regulatory commission or an agreement state.

(3) The person shall ensure that any labels required to be affixed to the device under rules of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited".

(4) The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04.

(5) The out-of-state licensee shall submit an annual reciprocity fee, as prescribed in chapter 33-10-11, at the time of ~~written notification~~ <u>initial request for reciprocity</u>.

c. The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by United States nuclear regulatory commission or an agreement state, or of any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

2. Licenses of naturally occurring and accelerator-produced radioactive material.

a. Subject to this article, any person who holds a specific license from a licensing state, and issued by the department having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty days in ~~any calendar year~~ the three hundred sixty-five day period the reciprocity agreement is active provided that all of the following requirements are met:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations.

(2) The out-of-state licensee notifies the department in writing, for each occurrence, at least three working days prior to engaging in such activity. Such notification must indicate the location, period, and type of proposed possession and use within the state, and must be accompanied by a copy of the pertinent licensing document and a copy of the licensee's operating and procedures manual. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of ~~the calendar year~~ the three hundred sixty-five day period the reciprocity agreement is active following the receipt of the initial notification from a person engaging in activities under the general license provided in subdivision a.

(3) The out-of-state licensee complies with this article and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with this article.

(4) The out-of-state licensee supplies such other information as the department may request.

(5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in subdivision a except by transfer to a person:

(a) Specifically licensed by the department or by another licensing state to receive such material, or

(b) Exempt from the requirements for a license for such material under subsection 2 of section 33-10-03-02.

(6) The out-of-state licensee shall submit an annual reciprocity fee, as described in chapter 33-10-11, at the time of ~~written notification~~ initial request for reciprocity.

b. Notwithstanding the provisions of subdivision a, any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in paragraph 1 of subdivision b of subsection 2 of section 33-10-03-04 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

(1) Such person shall file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report must identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a licensing state;

(3) Such person shall assure that any labels required to be affixed to the device under rules of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited";

(4) The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in subdivision b of subsection 2 of section 33-10-03-04 or in equivalent regulations of another licensing state having jurisdiction over the manufacture and distribution of the device; and

(5) The out-of-state licensee shall submit an annual reciprocity fee, as prescribed in chapter 33-10-11, at the time of ~~written notification~~ initial request for reciprocity.

c. The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document

issued by a licensing state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

3. Deliberate misconduct. This subsection gives notice to all persons who knowingly provide to any licensee, applicant for a license or certificate or quality assurance program approval, holder of a certificate or quality assurance program approval, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's or applicant's activities subject to article 33-10, that they may be individually subject to department enforcement action for violation of sections 33-10-03-09 or 33-10-13-22.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992.
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

33-10-03-07. Transportation. Repealed effective June 1, 1992.

33-10-03-08. Completeness and accuracy of information.

1. Information provided to the department by an applicant for a license or by a licensee or information required by statute or by article 33-10, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

2. Each applicant or licensee shall notify the department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this subsection only if the applicant or licensee fails to notify the department of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the department within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the department by other reporting or updating requirements.

33-10-03-09. Deliberate misconduct.

1. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor

(including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in article 33-10, may not:

a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the department; or

b. Deliberately submit to the department, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the department.

2. A person who violates subsection 1 may be subject to enforcement action.

3. For the purposes of subdivision a of subsection 1, deliberate misconduct by a person means an intentional act or omission that the person knows:

a. Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the department; or

b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

33-10-03-10. Records.

1. Each person who receives radioactive material pursuant to a license issued pursuant to article 33-10 shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

a. The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

b. The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.

c. The licensee who disposed of the material shall retain each record of disposal of radioactive material until the department terminates each license that authorizes disposal of the material.

2. The licensee shall retain each record that is required by article 33-10 or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

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

b. If there is a conflict between article 33-10, license condition, or other written department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in article 33-10 for such records shall apply unless the department, pursuant to section 33-10-01-05, has granted a specific exemption from the record retention requirements specified in article 33-10.

4. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than one hundred twenty days, in an unsealed form, shall forward the following records to the department:

a. Records of disposal of radioactive material made under subsections 2, 3, 4, and 5 of section 33-10-04.1-14. This includes records of any disposals of radioactive material by burial in soil, authorized prior to October 1, 1982.

b. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment, required by paragraph 4 of subdivision b of subsection 3 of section 33-10-04.1-15.

5. If licensed activities are transferred or assigned in accordance with subsection 4 of section 33-10-03-04 or in accordance with subdivision b of subsection 7 of section 33-10-03-05, each licensee authorized to possess radioactive material, with a half-life greater than one hundred twenty days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

   a. Records of disposal of radioactive material made under subsections 2, 3, 4, and 5 of section 33-10-04.1-14. This includes records of any disposals of radioactive material by burial in soil, authorized prior to October 1, 1982.

   b. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment, required by paragraph 4 of subdivision b of subsection 3 of section 33-10-04.1-15.

6. Prior to license termination, each licensee shall forward the records required by subdivision g of subsection 14 of section 33-10-03-05 (records of information important to the decommissioning of a facility) to the department.

SCHEDULE A
EXEMPT CONCENTRATIONS

Element (Atomic Number)	Radionuclide	Column I Gas Concentration $\mu Ci/ml$ [1/]	Column II Liquid and Solid Concentration $\mu Ci/ml$ [2/]
Antimony (51)	Sb-122		$3x10^{-4}$
	Sb-124		$2x10^{-4}$
	Sb-125		$1x10^{-3}$
Argon (18)	Ar-37	$1x10^{-3}$	
	Ar-41	$4x10^{-7}$	
Arsenic (33)	As-73		$5x10^{-3}$
	As-74		$5x10^{-4}$
	As-76		$2x10^{-4}$
	As-77		$8x10^{-4}$
Barium (56)	Ba-131		$2x10^{-3}$
	Ba-140		$3x10^{-4}$
Beryllium (4)	Be-7		$2x10^{-2}$
Bismuth (83)	Bi-206		$4x10^{-4}$
Bromine (35)	Br-82	$4x10^{-7}$	$3x10^{-3}$
Cadmium (48)	Cd-109		$2x10^{-3}$
	Cd-115m		$3x10^{-4}$
	Cd-115		$3x10^{-4}$
Calcium (20)	Ca-45		$9x10^{-5}$
	Ca-47		$5x10^{-4}$
Carbon (6)	C-14	$1x10^{-6}$	$8x10^{-3}$
Cerium (58)	Ce-141		$9x10^{-4}$
	Ce-143		$4x10^{-4}$
	Ce-144		$1x10^{-4}$
Cesium (55)	Cs-131		$2x10^{-2}$
	Cs-134m		$6x10^{-2}$
	Cs-134		$9x10^{-5}$
Chlorine (17)	Cl-38	$9x10^{-7}$	$4x10^{-3}$
Chromium (24)	Cr-51		$2x10^{-2}$
Cobalt (27)	Co-57		$5x10^{-3}$
	Co-58		$1x10^{-3}$
	Co-60		$5x10^{-4}$
Copper (29)	Cu-64		$3x10^{-3}$
Dysprosium (66)	Dy-165		$4x10^{-3}$
	Dy-166		$4x10^{-4}$
Erbium (68)	Er-169		$9x10^{-4}$
	Er-171		$1x10^{-3}$
Europium (63)	Eu-152 (T_r=9.2 h)		$6x10^{-4}$
	Eu-155		$2x10^{-3}$
Fluorine (9)	F-18	$2x10^{-6}$	$8x10^{-3}$

[1/] Values are given in Column I only for those materials normally used as gases.
[2/] $\mu Ci/g$ for solids.

Element (Atomic Number)	Radionuclide	Column I Gas Concentration $\mu Ci/ml^{1/}$	Column II Liquid and Solid Concentration $\mu Ci/ml^{2/}$
Gadolinium (64)	Gd-153		$2x10^{-3}$
	Gd-159		$8x10^{-4}$
Gallium (31)	Ga-72		$4x10^{-4}$
Germanium (32)	Ge-71		$2x10^{-2}$
Gold (79)	Au-196		$2x10^{-3}$
	Au-198		$5x10^{-4}$
	Au-199		$2x10^{-3}$
Hafnium (72)	Hf-181		$7x10^{-4}$
Hydrogen (1)	H-3	$5x10^{-6}$	$3x10^{-2}$
Indium (49)	In-113m		$1x10^{-2}$
	In-114m		$2x10^{-4}$
Iodine (53)	I-126	$3x10^{-9}$	$2x10^{-5}$
	I-131	$3x10^{-9}$	$2x10^{-5}$
	I-132	$8x10^{-8}$	$6x10^{-4}$
	I-133	$1x10^{-8}$	$7x10^{-5}$
	I-134	$2x10^{-7}$	$1x10^{-3}$
Iridium (77)	Ir-190		$2x10^{-3}$
	Ir-192		$4x10^{-4}$
	Ir-194		$3x10^{-4}$
Iron (26)	Fe-55		$8x10^{-3}$
	Fe-59		$6x10^{-4}$
Krypton (36)	Kr-85m	$1x10^{-6}$	
	Kr-85	$3x10^{-6}$	
Lanthanum (57)	La-140		$2x10^{-4}$
Lead (82)	Pb-203		$4x10^{-3}$
Lutetium (71)	Lu-177		$1x10^{-3}$
Manganese (25)	Mn-52		$3x10^{-4}$
	Mn-54		$1x10^{-3}$
	Mn-56		$1x10^{-3}$
Mercury (80)	Hg-197m		$2x10^{-3}$
	Hg-197		$3x10^{-3}$
	Hg-203		$2x10^{-4}$
Molybdenum (42)	Mo-99		$2x10^{-3}$
Neodymium (60)	Nd-147		$6x10^{-4}$
	Nd-149		$3x10^{-3}$
Nickel (28)	Ni-65		$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1x10^{-3}$
	Nb-97		$9x10^{-3}$
Osmium (76)	Os-185		$7x10^{-4}$
	Os-191m		$3x10^{-2}$
	Os-191		$2x10^{-3}$
	Os-193		$6x10^{-4}$
Palladium (46)	Pd-103		$3x10^{-3}$
	Pd-109		$9x10^{-4}$
Phosphorus (15)	P-32		$2x10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu Ci/g$ for solids.

Element (Atomic Number)	Radionuclide	Column I Gas Concentration $\mu Ci/ml^{1/}$	Column II Liquid and Solid Concentration $\mu Ci/ml^{2/}$
Platinum (78)	Pt-191		$1x10^{-3}$
	Pt-193m		$1x10^{-2}$
	Pt-197m		$1x10^{-2}$
	Pt-197		$1x10^{-3}$
Potassium (19)	K-42		$3x10^{-3}$
Praseodymium (59)	Pr-142		$3x10^{-4}$
	Pr-143		$5x10^{-4}$
Promethium (61)	Pm-147		$2x10^{-3}$
	Pm-149		$4x10^{-4}$
Rhenium (75)	Re-183		$6x10^{-3}$
	Re-186		$9x10^{-4}$
	Re-188		$6x10^{-4}$
Rhodium (45)	Rh-103m		$1x10^{-1}$
	Rh-105		$1x10^{-3}$
Rubidium (37)	Rb-86		$7x10^{-4}$
Ruthenium (44)	Ru-97		$4x10^{-3}$
	Ru-103		$8x10^{-4}$
	Ru-105		$1x10^{-3}$
	Ru-106		$1x10^{-4}$
Samarium (62)	Sm-153		$8x10^{-4}$
Scandium (21)	Sc-46		$4x10^{-4}$
	Sc-47		$9x10^{-4}$
	Sc-48		$3x10^{-4}$
Selenium (34)	Se-75		$3x10^{-3}$
Silicon (14)	Si-31		$9x10^{-3}$
Silver (47)	Ag-105		$1x10^{-3}$
	Ag-110m		$3x10^{-4}$
	Ag-111		$4x10^{-4}$
Sodium (11)	Na-24		$2x10^{-3}$
Strontium (38)	Sr-85		$1x10^{-3}$
	Sr-89		$1x10^{-4}$
	Sr-91		$7x10^{-4}$
	Sr-92		$7x10^{-4}$
Sulfur (16)	S-35	$9x10^{-8}$	$6x10^{-4}$
Tantalum (73)	Ta-182		$4x10^{-4}$
Technetium (43)	Tc-96m		$1x10^{-1}$
	Tc-96		$1x10^{-3}$
Tellurium (52)	Te-125m		$2x10^{-3}$
	Te-127m		$6x10^{-4}$
	Te-127		$3x10^{-3}$
	Te-129m		$3x10^{-4}$
	Te-131m		$6x10^{-4}$
	Te-132		$3x10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ $\mu Ci/g$ for solids.

Element (Atomic Number)	Radionuclide	Column I Gas Concentration $\mu Ci/ml^{1/}$	Column II Liquid and Solid Concentration $\mu Ci/ml^{2/}$
Terbium (65)	Tb-160		$4x10^{-4}$
Thallium (81)	Tl-200		$4x10^{-3}$
	Tl-201		$3x10^{-3}$
	Tl-202		$1x10^{-3}$
	Tl-204		$1x10^{-3}$
Thulium (69)	Tm-170		$5x10^{-4}$
	Tm-171		$5x10^{-3}$
Tin (50)	Sn-113		$9x10^{-4}$
	Sn-125		$2x10^{-4}$
Tungsten (Wolfram)(74)	W-181		$4x10^{-3}$
	W-187		$7x10^{-4}$
Vanadium (23)	V-48		$3x10^{-4}$
Xenon (54)	Xe-131m	$4x10^{-6}$	
	Xe-133	$3x10^{-6}$	
	Xe-135	$1x10^{-6}$	
Ytterbium (70)	Yb-175		$1x10^{-3}$
Yttrium (39)	Y-90		$2x10^{-4}$
	Y-91m		$3x10^{-2}$
	Y-91		$3x10^{-4}$
	Y-92		$6x10^{-4}$
	Y-93		$3x10^{-4}$
Zinc (30)	Zn-65		$1x10^{-3}$
	Zn-69m		$7x10^{-4}$
	Zn-69		$2x10^{-2}$
Zirconium (40)	Zr-95		$6x10^{-4}$
	Zr-97		$2x10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.		$1x10^{-10}$	$1x10^{-6}$

1/ Values are given in Column I only for those materials normally used as gases.
2/ $\mu Ci/g$ for solids.

NOTE 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Schedule A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

NOTE 2: For purposes of subsection 2 of section 33-10-03-02 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A

for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1".

EXAMPLE:

$$\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} +$$

$$\frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} < 1$$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter, multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 (2×10^{-4} μCi/ml multiplied by 37 is equivalent to 74×10^{-4} megabecquerels per liter).

SCHEDULE B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10

Radioactive Material	Microcuries
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10

Radioactive Material	Microcuries
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10

Radioactive Material	Microcuries
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

Note 1: For purposes of subparagraph (b) of paragraph (5) of subdivision g of subsection 2 of section 33-10-03-05 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Schedule B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed one.

Example:

$$\frac{\text{Amt. of Radionuclide A possessed}}{\text{1000 x Schedule B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{\text{1000 x Schedule B quantity for Radionuclide B}} < 1$$

Note 2: To convert microcuries to SI units of kilobecquerels, multiply the above values by 37.

Example: Zirconium-97 (10 microcuries multiplied by 37 is equivalent to 370 kilobecquerels).

History: Amended effective June 1, 1992; May 1, 1998.

SCHEDULE C
LIMITS FOR BROAD LICENSES
(SUBSECTION 4 OF SECTION 33-10-03-05)

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

Note: To convert curies to the SI units gigabecquerels, multiply the above values by 37.

Example: Zirconium-97 (Col. II) (0.01 curies multiplied by 37 is equivalent to 0.37 gigabecquerels).

SCHEDULE D

CRITERIA ~~RELATED~~ RELATING TO THE OPERATION OF URANIUM MILLS AND THE DISPOSITION OF ~~URANIUM MILL~~ TAILINGS OR WASTES PRODUCED BY THE EXTRACTION OR CONCENTRATION OF SOURCE MATERIAL FROM ORES PROCESSED PRIMARILY FOR THEIR SOURCE MATERIAL CONTENT

INTRODUCTION - As required by subdivision ~~m~~ 1 of subsection 5 of section 33-10-03-05, ~~each~~ every applicant for a license to possess and use source material in conjunction with uranium or thorium milling, or byproduct material at sites formerly associated with such milling, is required to include in a license application proposed specifications relating to milling operations and the disposition of tailings or wastes resulting from such milling activities. This schedule establishes technical, financial, ownership, and long-term site surveillance criteria relating to the siting, operation, decontamination, decommissioning, and reclamation of mills and tailings or waste systems and sites at which such mills and systems are located. As used in this schedule, the term "as low as is reasonably achievable" has the same meaning as in section 33-10-01-04 ~~subsection 2 of section 33-10-04.1-05~~.

In many cases, flexibility is provided in the criteria to allow achieving an optimum tailings disposal program on a site-specific basis. However, in such cases the objectives, technical alternatives, and concerns which must be taken into account in developing a tailings program are identified. As provided by the provisions of paragraph 7 of subdivision 1 of subsection 5 of section 33-10-03-05, ~~A~~applications for licenses must clearly demonstrate how the criteria have been addressed.

The specifications shall be developed considering the expected full capacity of tailings or waste systems and the lifetime of mill operations. Where later expansions of systems or operations may be likely (for example, where large quantities of ore now marginally uneconomical may be stockpiled), the amenability of the disposal system to accommodate increased capacities without degradation in long-term stability and other performance factors shall be evaluated.

~~Detailed programs meeting the technical and financial criteria in this schedule including appropriate supporting data, analyses, and alternatives, shall be developed by existing uranium milling licensees and filed, in connection with license renewal applications or within nine months from the effective date of this schedule whichever occurs first.~~

Licensees or applicants may propose alternatives to the specific requirements in this schedule. The alternative proposals may take into account local or regional conditions, including geology,

topography, hydrology, and meteorology. The department may find that the proposed alternatives meet the department's requirements if the alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with the sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by the requirements of this schedule and the standards promulgated by the United States environmental protection agency in 40 CFR part 192, subparts D and E.

All site-specific licensing decisions based on the criteria in this schedule or alternatives proposed by licensees or applicants will take into account the risk to the public health and safety and the environment with due consideration to the economic costs involved and any other factors the department determines to be appropriate. In implementing this schedule, the department will consider "practicable" and "reasonably achievable" as equivalent terms. Decisions involving these terms will take into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

The following definitions apply to the specified terms as used in this schedule:

"Aquifer" means a geologic formation, group of formations, or part of a formation capable of yielding a significant amount of ground water to wells or springs. Any saturated zone created by uranium or thorium recovery operations would not be considered an aquifer unless the zone is or potentially is (1) hydraulically interconnected to a natural aquifer, (2) capable of discharge to surface water, or (3) reasonably accessible because of migration beyond the vertical projection of the boundary of the land transferred for long-term government ownership and care in accordance with criterion 11 of this schedule.

"As expeditiously as practicable considering technological feasibility", for the purposes of criterion 6A, means as quickly as possible considering: the physical characteristics of the tailings and the site; the limits of "available technology"; the need for consistency with mandatory requirements of other regulatory programs; and "factors beyond the control of the licensee". The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term "available technology".

"Available technology" means technologies and methods for emplacing a final radon barrier on uranium mill tailings piles or

impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry (or one that is reasonably analogous), (such as, by way of illustration only, unreasonable overtime, staffing, or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils, etc.), provided there is reasonable progress toward emplacement of the final radon barrier. To determine grossly excessive costs, the relevant baseline against which cost shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's approved reclamation plan, but costs beyond these estimates shall not automatically be considered grossly excessive.

"Closure" means the activities following operations to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings or waste disposal area.

"Closure plan" means the department-approved plan to accomplish closure.

"Compliance period" begins when the department sets secondary ground-water protection standards and ends when the owner or operator's license is terminated and the site is transferred to the state or federal agency for long-term care.

"Dike" means an embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids or other materials.

"Disposal area" means the area containing byproduct materials to which the requirements of criterion 6 apply.

"Existing portion" means that land surface area of an existing surface impoundment on which significant quantities of uranium or thorium byproduct materials had been placed prior to September 30, 1983.

"Factors beyond the control of the licensee" means factors proximately causing delay in meeting the schedule in the applicable reclamation plan for the timely emplacement of the final radon barrier notwithstanding the good faith efforts of the licensee to complete the barrier in compliance with paragraph (1) of criterion 6A. These factors may include, but are not limited to--

(1) Physical conditions at the site;
(2) Inclement weather or climatic conditions;
(3) An act of God;
(4) An act of war;
(5) A judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements

applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance;

(6) Labor disturbances;

(7) Any modifications, cessation or delay ordered by state, federal, or local agencies;

(8) Delays beyond the time reasonably required in obtaining necessary government permits, licenses, approvals, or consent for activities described in the reclamation plan proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the reclamation plan; and

(9) An act or omission of any third party over whom the licensee has no control.

"Final radon barrier" means the earthen cover (or approved alternative cover) over tailings or waste constructed to comply with criterion 6 of this schedule (excluding erosion protection features).

"Ground water" means water below the land surface in a zone of saturation. For purposes of this schedule, ground water is the water contained within an aquifer as defined above.

"Leachate" means any liquid, including any suspended or dissolved components in the liquid, that has percolated through or drained from the byproduct material.

"Licensed site" means the area contained within the boundary of a location under the control of persons generating or storing byproduct materials under a department license.

"Liner" means a continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment which restricts the downward or lateral escape of byproduct material, hazardous constituents, or leachate.

"Milestone" means an action or event that is required to occur by an enforceable date.

"Operation" means that a uranium or thorium mill tailings pile or impoundment is being used for the continued placement of byproduct material or is in standby status for such placement. A pile or impoundment is in operation from the day that byproduct material is first placed in the pile or impoundment until the day final closure begins.

"Point of compliance" is the site-specific location in the uppermost aquifer where the ground-water protection standard must be met.

"Reclamation plan", for the purposes of criterion 6A, means the plan detailing activities to accomplish reclamation of the tailings or waste disposal area in accordance with the technical criteria of this schedule. The reclamation plan must include a timetable for reclamation milestones that are key to the completion of the final radon barrier including as appropriate, but not limited to, wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and final radon barrier construction. (Reclamation of tailings must also be addressed in the closure plan; the detailed reclamation plan may be incorporated into the closure plan.)

"Surface impoundment" means a natural topographic depression, man-made excavation, or diked area, which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well.

"Uppermost aquifer" means the geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

I. Technical Criteria

CRITERION 1 - The general goal or broad objective in siting and design decisions is permanent isolation of tailings and associated contaminants by minimizing disturbance and dispersion by natural forces, and to do so without ongoing maintenance. For practical reasons, specific siting decisions and design standards must involve finite times (e.g., the longevity design standard in criterion 6). The following site features which will contribute to such a goal or objective must be considered in selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites: ~~In selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites, the following site features, which will determine the extent to which a program meets the broad objective of isolating the tailings and associated contaminants from man and the environment during operations and for thousands of years thereafter without ongoing active maintenance, shall be considered:~~

- remoteness from populated areas;
- hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from ~~useable~~ ground water sources; and

- potential ~~of~~ for minimizing erosion, disturbance, and dispersion by natural forces over the long-term.

The site selection process shall be an optimization to the maximum extent reasonably achievable in terms of these features.

In the selection of disposal sites, primary emphasis shall be given to isolation of tailings or wastes, a matter having long-term impacts, as opposed to consideration only of short-term convenience or benefits, such as minimization of transportation or land acquisition costs. While isolation of tailings will be a function of both site ~~characteristics~~ and engineering design, overriding consideration shall be given to siting features given the long-term nature of the tailings hazards.

Tailings shall be disposed of in a manner ~~such~~ that no active maintenance is required to preserve the condition of the site.

CRITERION 2 - To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material from ~~insite~~ in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote aboveground extraction operations shall ~~preferably~~ be disposed of at existing large mill tailings disposal sites; unless, considering the nature of the wastes, such as their volume and specific activity and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable ~~impractical~~ or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.

CRITERION 3 - The "prime option" for disposal of tailings is placement below grade, either in mines or specially excavated pits (that is, where ~~when~~ the need for any specially constructed retention structure is eliminated). The evaluation of alternative sites and disposal methods performed by mill operators in support of their proposed tailings disposal program (provided in applicants' environmental reports) shall reflect serious consideration of this disposal mode. In some instances, below-grade disposal may not be the most environmentally sound approach, such as might be the case if a ~~high quality~~ ground water formation is relatively close to the surface or not very well isolated by overlying soils and rock. Also, geologic and topographic conditions might make full, below-grade burial impracticable ~~impractical~~; for example, bedrock may be sufficiently near the surface that blasting would be required to excavate a disposal pit at excessive cost, and more suitable alternate sites are not available. Where full below-grade burial is not practicable ~~practical~~, the size of retention structures, and size and steepness of slopes of associated exposed embankments,

shall be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic ~~hydrogeologic~~ conditions at a site. In these cases, it must be demonstrated that an above-grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

CRITERION 4 - The following site and design criteria shall be adhered to whether tailings or wastes are disposed of above or below grade:

(a) Upstream rainfall catchment areas must be minimized to decrease erosion potential and the size of the ~~maximum possible~~ floods which could erode or wash out sections of the tailings disposal area.

(b) Topographic features shall provide good wind protection.

(c) Embankment and cover slopes shall be relatively flat after final stabilization to minimize erosion potential and to provide conservative factors of safety assuring long-term stability. The broad objective should be to contour final slopes to grades which are as close as possible to those which would be provided if tailings were disposed of below grade; this could, for example, lead to slopes of about ten horizontal to one vertical (10h:1v) or less steep. In general, slopes should not be steeper than about 5h:1v. Where steeper slopes are proposed, reasons why a slope less steep than 5h:1v would be impracticable ~~impractical~~ should be provided, and compensating factors and conditions which make such slopes acceptable should be identified.

(d) A full self-sustaining vegetative cover shall be established or rock cover employed to reduce wind and water erosion to negligible levels.

Where a full vegetative cover is not likely to be self-sustaining due to climatic or other conditions, such as in semi-arid and arid regions, rock cover shall be employed on slopes of the impoundment system. The ~~staff~~ department will consider relaxing this requirement for extremely gentle slopes such as those which may exist on the top of the pile.

The following factors shall be considered in establishing the final rock cover design to avoid displacement of rock particles by human and animal traffic or by natural processes, and to preclude undercutting and piping:

- shape, size, composition, gradation of rock particles (excepting bedding material, average particle size shall be at least cobble size or greater);

- rock cover thickness and zoning of particles by size; and

- steepness of underlying slopes.

Individual rock fragments shall be dense, sound, and resistant to abrasion, and shall be free from cracks, seams, and other defects that would tend to unduly increase their destruction by water and frost actions. Weak, friable, or laminated aggregate shall not be used. Shale, rock~~,~~ laminated with shale, and cherts shall not be used.

Rock covering of slopes may not be required where top covers are very thick (on the order of ~~eighteen~~ ten meters or greater); impoundment slopes are very gentle (on the order of 10h:1v or less); bulk cover materials have inherently favorable erosion resistance characteristics; and there is negligible drainage catchment area upstream of the pile, and there is good wind protection as described in points (a) and (b) of this criterion.

Furthermore, all impoundment surfaces shall be contoured to avoid areas of concentrated surface runoff or abrupt or sharp changes in slope gradient. In addition to rock cover on slopes, areas toward which surface runoff might be directed shall be well protected with substantial rock cover (riprap). In addition to providing for stability of the impoundment system~~s~~ itself, overall stability, erosion potential, and geomorphology of surrounding terrain shall be evaluated to assure that there are no ongoing or potential processes, such as gully erosion, which would lead to impoundment instability.

(e) The impoundment shall not be located near a capable fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand. As used in this criterion, the term "capable fault" has the same meaning as defined in Section III (g) of Appendix A of 10 CFR Part 100. The term "maximum credible earthquake" means that earthquake which would cause the maximum vibratory ground motion based upon an evaluation of earthquake potential considering the regional and local geology and seismology

and specific characteristics of local subsurface material.

(f) The impoundment, where feasible, should be designed to incorporate features which will promote deposition. For example, design features which promote deposition of sediment suspended in any runoff which flows into the impoundment area might be utilized; the object of such a design feature would be to enhance the thickness of cover over time.

CRITERION 5 - ~~Steps shall be taken to reduce seepage of toxic materials into groundwater to the maximum extent reasonably achievable. Any seepage which does occur shall not result in deterioration of existing groundwater supplies from their current or potential use. The following shall be considered to accomplish this.~~

- ~~Installation of low permeability bottom liners (where synthetic liners are used, a leakage detection system shall be installed immediately below the liner to ensure major failures are detected if they occur. This is in addition to the groundwater monitoring program conducted as provided in Criterion 7. Where clay liners are proposed or relatively thin in-site clay soils are to be relied upon for seepage control, tests shall be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests shall be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases, deterioration has been observed to occur rather rapidly after about nine months of exposure).~~

- ~~Mill process design which provides the maximum practical recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.~~

- ~~Dewatering of tailings by process devices or in situ drainage system. At new sites, tailings shall be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head for seepage, unless tests show tailings are not amenable to such a system. Where in-situ dewatering is to be conducted, the impoundment bottom shall be graded to assure that the drains are at a low point. The drains shall be protected by suitable filter materials to assure that drains remain free running. The~~

~~drainage system shall also be adequately sized to assure good drainage.~~

- ~~Neutralization to promote immobilization of toxic substances.~~

~~Where groundwater impacts are occurring at an existing site due to seepage, action shall be taken to alleviate conditions that lead to excessive seepage impacts and restore groundwater quality to its potential use before milling operations began to the maximum extent practical. The specific seepage control and groundwater protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications shall be prepared to control installation of seepage control systems. A quality assurance, testing and inspection program, which includes supervision by a qualified engineer or geologist, shall be established to assure that specification is met.~~

~~While the primary method of protecting groundwater shall be isolation of tailings and tailings solutions, disposal involving contact with groundwater will be considered provided supporting tests and analysis are presented demonstrating that the proposed disposal and treatment methods will not degrade groundwater from current or potential uses.~~

~~Furthermore, steps shall be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils, suitable methods include lining or compaction of ore storage areas.~~

~~In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following.~~

- ~~The chemical and radioactive characteristics of the waste solutions.~~

- ~~The characteristics of the underlying soil and geologic formations particularly the extent to which they will control transport of contaminants and solutions. This shall include detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations shall be determined.~~

- ~~This information shall be gathered by borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to usable ground water. The information gathered on boreholes shall include both geologic and geophysical~~

~~logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits which are of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability shall not be determined on the basis of laboratory analysis of samples alone, a sufficient amount of field testing (e.g., pump tests) shall be conducted to assure actual field properties are adequately understood. Testing shall be conducted to allow estimating chemisorption attenuation properties of underlying soil and rock.~~

~~Location, extent, quality, and capacity of any ground water at and near the site.~~

Criteria 5A-5D and criterion 13 incorporate the basic ground-water protection standards imposed by the United States environmental protection agency in 40 CFR part 192, subparts D and E (48 FR 45926; October 7, 1983) which apply during operations and prior to the end of closure. Ground-water monitoring to comply with these standards is required by criterion 7A.

5A(1)--The primary ground-water protection standard is a design standard for surface impoundments used to manage uranium and thorium byproduct material. Unless exempted under paragraph 5A(3) of this criterion, surface impoundments (except for an existing portion) must have a liner that is designed, constructed, and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil, ground water, or surface water at any time during the active life (including the closure period) of the impoundment. The liner may be constructed of materials that may allow wastes to migrate into the liner (but not into the adjacent subsurface soil, ground water, or surface water) during the active life of the facility, provided that impoundment closure includes removal or decontamination of all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate. For impoundments that will be closed with the liner material left in place, the liner must be constructed of materials that can prevent wastes from migrating into the liner during the active life of the facility.

5A(2)--The liner required by paragraph 5A(1) above must be-

(a) Constructed of materials that have appropriate chemical properties and sufficient strength and thickness to prevent failure due to pressure gradients (including static head and external hydrogeologic forces), physical

contact with the waste or leachate to which they are exposed, climatic conditions, the stress of installation, and the stress of daily operation;

(b) Placed upon a foundation or base capable of providing support to the liner and resistance to pressure gradients above and below the liner to prevent failure of the liner due to settlement, compression, or uplift; and

(c) Installed to cover all surrounding earth likely to be in contact with the wastes or leachate.

5A(3)--The applicant or licensee will be exempted from the requirements of paragraph 5A(1) of this criterion if the department finds, based on a demonstration by the applicant or licensee, that alternate design and operating practices, including the closure plan, together with site characteristics will prevent the migration of any hazardous constituents into ground water or surface water at any future time. In deciding whether to grant an exemption, the department will consider-

(a) The nature and quantity of the wastes;

(b) The proposed alternate design and operation;

(c) The hydrogeologic setting of the facility, including the attenuative capacity and thickness of the liners and soils present between the impoundment and ground water or surface water; and

(d) All other factors which would influence the quality and mobility of the leachate produced and the potential for it to migrate to ground water or surface water.

5A(4)--A surface impoundment must be designed, constructed, maintained, and operated to prevent overtopping resulting from normal or abnormal operations, overfilling, wind and wave actions, rainfall, or run-on; from malfunctions of level controllers, alarms, and other equipment; and from human error.

5A(5)--When dikes are used to form the surface impoundment, the dikes must be designed, constructed, and maintained with sufficient structural integrity to prevent massive failure of the dikes. In ensuring structural integrity, it must not be presumed that the liner system will function without leakage during the active life of the impoundment.

5B(1)--Uranium and thorium byproduct materials must be managed to conform to the following secondary ground-water protection standard:

Hazardous constituents entering the ground water from a licensed site must not exceed the specified concentration limits in the uppermost aquifer beyond the point of compliance during the compliance period. Hazardous constituents are those constituents identified by the department pursuant to paragraph 5B(2) of this criterion. Specified concentration limits are those limits established by the department as indicated in paragraph 5B(5) of this criterion. The department will also establish the point of compliance and compliance period on a site specific basis through license conditions and orders. The objective in selecting the point of compliance is to provide the earliest practicable warning that the impoundment is releasing hazardous constituents to the ground water. The point of compliance must be selected to provide prompt indication of ground-water contamination on the hydraulically downgradient edge of the disposal area. The department shall identify hazardous constituents, establish concentration limits, set the compliance period, and may adjust the point of compliance if needed to accord with developed data and site information as to the flow of ground water or contaminants, when the detection monitoring established under criterion 7A indicates leakage of hazardous constituents from the disposal area.

5B(2)--A constituent becomes a hazardous constituent subject to paragraph 5B(5) only when the constituent meets all three of the following tests:

(a) The constituent is reasonably expected to be in or derived from the byproduct material in the disposal area;

(b) The constituent has been detected in the ground water in the uppermost aquifer; and

(c) The constituent is listed in criterion 13 of this schedule.

5B(3)--Even when constituents meet all three tests in paragraph 5B(2) of this criterion, the department may exclude a detected constituent from the set of hazardous constituents on a site specific basis if it finds that the constituent is not capable of posing a substantial present or potential hazard to human health or the environment. In deciding whether to exclude constituents, the department will consider the following:

(a) Potential adverse effects on ground-water quality, considering--
  (i) The physical and chemical characteristics of the waste in the licensed site, including its potential for migration;
  (ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity of ground water and the direction of ground-water flow;

(iv) The proximity and withdrawal rates of ground-water users;

(v) The current and future uses of ground water in the area;

(vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(vii) The potential for health risks caused by human exposure to waste constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(ix) The persistence and permanence of the potential adverse effects.

(b) Potential adverse effects on hydraulically-connected surface water quality, considering--

(i) The volume and physical and chemical characteristics of the waste in the licensed site;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity and quality of ground water, and the direction of ground-water flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the licensed site to surface waters;

(vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(vii) The existing quality of surface water, including other sources of contamination and the cumulative impact on surface-water quality;

(viii) The potential for health risks caused by human exposure to waste constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(x) The persistence and permanence of the potential adverse effects.

5B(4)--In making any determinations under paragraphs 5B(3) and 5B(6) of this criterion about the use of ground water in the area around the facility, the department will consider any identification of underground sources of drinking water and exempted aquifers made by the United States environmental protection agency or the department.

5B(5)--At the point of compliance, the concentration of a hazardous constituent must not exceed-

(a) The department approved background concentration of that constituent in the ground water;

(b) The respective value given in the table in paragraph 5C if the constituent is listed in the table and if the background level of the constituent is below the value listed; or

(c) An alternate concentration limit established by the department.

5B(6)--Conceptually, background concentrations pose no incremental hazards and the drinking water limits in paragraph 5C state acceptable hazards but these two options may not be practically achievable at a specific site. Alternate concentration limits that present no significant hazard may be proposed by licensees for department consideration. Licensees must provide the basis for any proposed limits including consideration of practicable corrective actions, that limits are as low as reasonably achievable, and information on the factors the department must consider. The department will establish a site specific alternate concentration limit for a hazardous constituent as provided in paragraph 5B(5) of this criterion if it finds that the proposed limit is as low as reasonably achievable, after considering practicable corrective actions, and that the constituent will not pose a substantial present or potential hazard to human health or the environment as long as the alternate concentration limit is not exceeded. In making the present and potential hazard finding, the department will consider the following factors:

(a) Potential adverse effects on ground-water quality, considering--

(i) The physical and chemical characteristics of the waste in the licensed site including its potential for migration;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity of ground water and the direction of ground-water flow;

(iv) The proximity and withdrawal rates of ground-water users;

(v) The current and future uses of ground water in the area;

(vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground-water quality;

(vii) The potential for health risks caused by human exposure to waste constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;

(ix) The persistence and permanence of the potential adverse effects.

(b) Potential adverse effects on hydraulically-connected surface water quality, considering--

(i) The volume and physical and chemical characteristics of the waste in the licensed site;

(ii) The hydrogeological characteristics of the facility and surrounding land;

(iii) The quantity and quality of ground water, and the direction of ground-water flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the licensed site to surface waters;

(vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;

(vii) The existing quality of surface water including other sources of contamination and the cumulative impact on surface water quality;

(viii) The potential for health risks caused by human exposure to waste constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and

(x) The persistence and permanence of the potential adverse effects.

5C--Maximum Values for Ground-Water Protection

Constituent or property	Maximum concentration
Milligrams per liter:	
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chromium	0.05
Lead	0.05
Mercury	0.002
Selenium	0.01
Silver	0.05
Endrin (1,2,3,4,10,10-hexachloro-1,7 -expoxy-1,4,4a,5, 6,7,8,9a-octahydro-1, 4-endo, endo-5,8-dimethano naphthalene)	0.0002
Lindane (1,2,3,4,5,6-hexachlorocyclohexane, gamma isomer)	0.004

Methoxychlor (1,1,1-Trichloro-2,2-bis (p-methoxyphenylethane)).....0.1
Toxaphene ($C_{10}H_{10}Cl_6$, Technical chlorinated camphene, 67-69 percent chlorine)..... 0.005
2,4-D (2,4-Dichlorophenoxyacetic acid)..... 0.1
2,4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid). 0.01

Picocuries per liter:
Combined radium-226 and radium-228..... 5
Gross alpha-particle activity (excluding radon and uranium when producing uranium byproduct material or radon and thorium when producing thorium byproduct material).....15

5D--If the ground-water protection standards established under paragraph 5B(1) of this criterion are exceeded at a licensed site, a corrective action program must be put into operation as soon as is practicable, and in no event later than eighteen months after the department finds that the standards have been exceeded. The licensee shall submit the proposed corrective action program and supporting rationale for department approval prior to putting the program into operation, unless otherwise directed by the department. The objective of the program is to return hazardous constituent concentration levels in ground water to the concentration limits set as standards. The licensee's proposed program must address removing the hazardous constituents that have entered the ground water at the point of compliance or treating them in place. The program must also address removing or treating in place any hazardous constituents that exceed concentration limits in ground water between the point of compliance and the downgradient facility property boundary. The licensee shall continue corrective action measures to the extent necessary to achieve and maintain compliance with the ground-water protection standard. The department will determine when the licensee may terminate corrective action measures based on data from the ground-water monitoring program and other information that provide reasonable assurance that the ground-water protection standard will not be exceeded.

5E--In developing and conducting ground-water protection programs, applicants and licensees shall also consider the following:

(1) Installation of bottom liners (Where synthetic liners are used, a leakage detection system must be installed immediately below the liner to ensure major failures are detected if they occur. This is in addition to the ground-water monitoring program conducted as provided in criterion 7. Where clay liners are proposed, or relatively thin, in-situ clay soils are to be relied upon

for seepage control, tests must be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests must be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases deterioration has been observed to occur rather rapidly after about nine months of exposure)).

(2) Mill process designs which provide the maximum practicable recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.

(3) Dewatering of tailings by process devices or in-situ drainage systems (At new sites, tailings must be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head of seepage, unless tests show tailings are not amenable to such a system. Where in-situ dewatering is to be conducted, the impoundment bottom must be graded to assure that the drains are at a low point. The drains must be protected by suitable filter materials to assure that drains remain free running. The drainage system must also be adequately sized to assure good drainage).

(4) Neutralization to promote immobilization of hazardous constituents.

5F--Where ground-water impacts are occurring at an existing site due to seepage, action must be taken to alleviate conditions that lead to excessive seepage impacts and restore ground-water quality. The specific seepage control and ground-water protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications must be prepared to control installation of seepage control systems. A quality assurance, testing, and inspection program, which includes supervision by a qualified engineer or scientist, must be established to assure the specifications are met.

5G--In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following:

(1) The chemical and radioactive characteristics of the waste solutions.

(2) The characteristics of the underlying soil and geologic formations particularly as they will control transport of contaminants and solutions. This includes detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations must be determined. This information must be gathered from borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to ground water. The information gathered on boreholes must include both geologic and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability may not be determined on the basis of laboratory analysis of samples alone; a sufficient amount of field testing (e.g., pump tests) must be conducted to assure actual field properties are adequately understood. Testing must be conducted to allow estimating chemi-sorption attenuation properties of underlying soil and rock.

(3) Location, extent, quality, capacity and current uses of any ground water at and near the site.

5H--Steps must be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils; suitable methods include lining or compaction of ore storage areas.

CRITERION 6 - ~~Sufficient earth cover, but not less than three meters, shall be placed over tailings or wastes at the end of milling operations to result in a calculated reduction in surface exhalation of radon emanating from the tailings or wastes to less than two picocuries per square meter per second. In computing required tailings cover thickness, moisture in soils in excess of amounts found normally in similar soils in similar circumstances shall not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer shall not be taken into account in determining the calculated radon exhalation level. If non-soil materials are proposed to reduce tailings covers to less than three meters, it must be demonstrated that such materials will not crack or degrade by differential settlement, weathering, or other mechanism over long-term time intervals. Near surface materials, i.e., within the top three meters, shall not include mine waste or rock that contains elevated levels of radium; soils used for near surface cover must be~~

~~essentially the same, as far as radioactivity is concerned, as that of surrounding soils.~~

(1) In disposing of waste byproduct material, licensees shall place an earthen cover (or approved alternative) over tailings or wastes at the end of milling operations and shall close the waste disposal area in accordance with a design[1] which provides reasonable assurance of control of radiological hazards to (i) be effective for one thousand years, to the extent reasonably achievable, and, in any case, for at least two hundred years, and (ii) limit releases of radon-222 from uranium byproduct materials, and radon-220 from thorium byproduct materials, to the atmosphere so as not to exceed an average[2] release rate of twenty picocuries per square meter per second (pCi/m^2s) to the extent practicable throughout the effective design life determined pursuant to (1)(i) of this criterion. In computing required tailings cover thicknesses, moisture in soils in excess of amounts found normally in similar soils in similar circumstances may not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer may not be taken into account in determining the calculated radon exhalation level. If non-soil materials are proposed as cover materials, it must be demonstrated that these materials will not crack or degrade by differential settlement, weathering, or other mechanism, over long-term intervals.

(2) As soon as reasonably achievable after emplacement of the final cover to limit releases of radon-222 from uranium byproduct material and prior to placement of erosion protection barriers or other features necessary for long-term control of the tailings, the licensee shall verify through appropriate testing and analysis that the

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[1] In the case of thorium byproduct materials, the standard applies only to design. Monitoring for radon emissions from thorium byproduct materials after installation of an appropriately designed cover is not required.

[2] This average applies to the entire surface of each disposal area over a period of a least one year, but a period short compared to one hundred years. Radon will come from both byproduct materials and from covering materials. Radon emissions from covering materials should be estimated as part of developing a closure plan for each site. The standard, however, applies only to emissions from byproduct materials to the atmosphere.

design and construction of the final radon barrier is effective in limiting releases of radon-222 to a level not exceeding twenty picocuries per square meter per second averaged over the entire pile or impoundment using the procedures described in 40 CFR part 61, appendix B, method 115, or another method of verification approved by the department as being at least as effective in demonstrating the effectiveness of the final radon barrier.

(3) When phased emplacement of the final radon barrier is included in the applicable reclamation plan, the verification of radon-222 release rates required in paragraph (2) of this criterion must be conducted for each portion of the pile or impoundment as the final radon barrier for that portion is emplaced.

(4) Within ninety days of the completion of all testing and analysis relevant to the required verification in paragraphs (2) and (3) of this criterion, the uranium mill licensee shall report to the department the results detailing the actions taken to verify that levels of release of radon-222 do not exceed twenty picocuries per square meter per second when averaged over the entire pile or impoundment. The licensee shall maintain records until termination of the license documenting the source of input parameters including the results of all measurements on which they are based, the calculations or analytical methods used to derive values for input parameters, and the procedure used to determine compliance. These records shall be kept in a form suitable for transfer to the custodial agency at the time of transfer of the site to the United States department of energy or a state for long-term care if requested.

(5) Near surface cover materials (i.e., within the top three meters) may not include waste or rock that contains elevated levels of radium; soils used for near surface cover must be essentially the same, as far as radioactivity is concerned, as that of surrounding surface soils. This is to ensure that surface radon exhalation is not significantly above background because of the cover material itself.

(6) The design requirements in this criterion for longevity and control of radon releases apply to any portion of a licensed or disposal site unless such portion contains a concentration of radium in land, averaged over areas of one hundred square meters, which, as a result of

byproduct material, does not exceed the background level by more than:

(i) Five picocuries per gram of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over the first fifteen centimeters below the surface, and (ii) fifteen picocuries per gram of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over fifteen-centimeter thick layers more than fifteen centimeters below the surface.

Byproduct material containing concentrations of radionuclides other than radium in soil, and surface activity on remaining structures, must not result in a total effective dose equivalent (TEDE) exceeding the dose from cleanup of radium contaminated soil to the above standard (benchmark dose), and must be at levels which are as low as is reasonably achievable. If more than one residual radionuclide is present in the same one hundred square-meter area, the sum of the ratios for each radionuclide of concentration present to the concentration limit will not exceed "1" (unity). A calculation of the potential peak annual total effective dose equivalent within one thousand years to the average member of the critical group that would result from applying the radium standard (not including radon) on the site must be submitted for approval. The use of decommissioning plans with benchmark doses which exceed one hundred millirems per year, before application of ALARA, requires the approval of the department. This requirement for dose criteria does not apply to sites that have decommissioning plans for soil and structures approved before June 11, 1999.

(7) The licensee shall also address the nonradiological hazards associated with the wastes in planning and implementing closure. The licensee shall ensure that disposal areas are closed in a manner that minimizes the need for further maintenance. To the extent necessary to prevent threats to human health and the environment, the licensee shall control, minimize, or eliminate post-closure escape of nonradiological hazardous constituents, leachate, contaminated rainwater, or waste decomposition products to the ground or surface waters or to the atmosphere.

Criterion 6A--

(1) For impoundments containing uranium byproduct materials, the final radon barrier must be completed as expeditiously as practicable considering technological feasibility after the pile or impoundment ceases operation in accordance with a written, department-approved reclamation plan. (The term "as expeditiously as practicable considering technological feasibility" as specifically defined in the introduction of this schedule includes factors beyond the control of the licensee.) Deadlines for completion of the final radon barrier and, if applicable, the following interim milestones must be established as a condition of the individual license: windblown tailings retrieval and placement on the pile and interim stabilization (including dewatering or the removal of freestanding liquids and recontouring). The placement of erosion protection barriers or other features necessary for long-term control of the tailings must also be completed in a timely manner in accordance with a written, department-approved reclamation plan.

(2) The department may approve a licensee's request to extend the time for performance of milestones related to emplacement of the final radon barrier if, after providing an opportunity for public participation, the department finds that the licensee has adequately demonstrated in the manner required in paragraph (2) of criterion 6 that releases of radon-222 do not exceed an average of twenty picocuries per square meter per second. If the delay is approved on the basis that the radon releases do not exceed twenty picocuries per square meter per second, a verification of radon levels, as required by paragraph (2) of criterion 6, must be made annually during the period of delay. In addition, once the department has established the date in the reclamation plan for the milestone for completion of the final radon barrier, the department may extend that date based on cost if, after providing an opportunity for public participation, the department finds that the licensee is making good faith efforts to emplace the final radon barrier, the delay is consistent with the definition of available technology, and the radon releases caused by the delay will not result in a significant incremental risk to the public health.

(3) The department may authorize by license amendment, upon licensee request, a portion of the impoundment to accept uranium byproduct material or such materials that are similar in physical, chemical, and radiological characteristics to the uranium mill tailings and

associated wastes already in the pile or impoundment, from other sources, during the closure process. No such authorization will be made if it results in a delay or impediment to emplacement of the final radon barrier over the remainder of the impoundment in a manner that will achieve levels of radon-222 releases not exceeding twenty picocuries per square meter per second averaged over the entire impoundment. The verification required in paragraph (2) of criterion 6 may be completed with a portion of the impoundment being used for further disposal if the department makes a final finding that the impoundment will continue to achieve a level of radon-222 releases not exceeding twenty picocuries per square meter per second averaged over the entire impoundment. In this case, after the final radon barrier is complete except for the continuing disposal area, (a) only byproduct material will be authorized for disposal, (b) the disposal will be limited to the specified existing disposal area, and (c) this authorization will only be made after providing opportunity for public participation. Reclamation of the disposal area, as appropriate, must be completed in a timely manner after disposal operations cease in accordance with paragraph (1) of criterion 6; however, these actions are not required to be complete as part of meeting the deadline for final radon barrier construction.

CRITERION 7 - ~~Milling operations shall be conducted so that all airborne effluent releases are reduced to as low as is reasonably achievable. The primary means of accomplishing this shall be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practical measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. Checks shall be made and logged hourly of all parameters, e.g., differential pressure and scrubber water flow rate, which determine the efficiency of yellowcake stack emission control equipment operation. It shall be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action shall be taken when performance is outside of prescribed ranges. Effluent control devices shall be operative at all times~~

~~during drying and packaging operations and whenever air is exhausting from the yellowcake stack.~~

~~Drying and packaging operations shall terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions shall be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations shall cease as soon as practical.~~

~~Operations may not be re-started after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All such cessations, corrective actions, and re-starts shall be reported to the department in writing, within ten days of the subsequent re-start.~~

~~To control dusting from tailings, that portion not covered by standing liquids shall be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is not exposed to wind. Consideration shall be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments since this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.~~

At least one full year prior to any major site construction, a preoperational monitoring program must be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program must be conducted to measure or evaluate compliance with applicable standards and rules; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

7A--The licensee shall establish a detection monitoring program needed for the department to set the site-specific ground water protection standards in paragraph 5B(1) of this schedule. For all monitoring under this paragraph the licensee or applicant will propose for department approval as license conditions which constituents are to be monitored on a site specific basis. A detection monitoring program has two purposes. The initial purpose of the program is to detect leakage of hazardous constituents from the disposal area so that the need to set ground water protection

standards is monitored. If leakage is detected, the second purpose of the program is to generate data and information needed for the department to establish the standards under criterion 5B. The data and information must provide a sufficient basis to identify those hazardous constituents which require concentration limit standards and to enable the department to set the limits for those constituents and the compliance period. They may also need to provide the basis for adjustments to the point of compliance. For licenses in effect September 30, 1983, the detection monitoring programs must have been in place by October 1, 1984. For licenses issued after September 30, 1983, the detection monitoring programs must be in place when specified by the department in orders or license conditions. Once ground water protection standards have been established pursuant to paragraph 5B(1), the licensee shall establish and implement a compliance monitoring program. The purpose of the compliance monitoring program is to determine that the hazardous constituent concentrations in ground water continue to comply with the standards set by the department. In conjunction with a corrective action program, the licensee shall establish and implement a corrective action monitoring program. The purpose of the corrective action monitoring program is to demonstrate the effectiveness of the corrective actions. Any monitoring program required by this paragraph may be based on existing monitoring programs to the extent the existing programs can meet the stated objective for the program.

CRITERION 8 - ~~These criteria relating to ownership of tailings and their disposal sites become effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.~~

~~Any uranium or thorium milling license or tailings license shall contain such terms and conditions as the United States nuclear regulatory commission determines necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.~~

~~Title to the byproduct material license pursuant to subdivision m of subsection 5 of section 33-10-03-05 and land, including any interests therein (other than land owned by the United States or by a state) which is used for the disposal of any such byproduct material, or is essential to ensure the long-term stability of such disposal site, shall be transferred to the United States or the state in which such land is located, at the option of such state. In view of the fact that physical isolation must be the primary means of long-term control, and government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests, for example, mineral rights, may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and~~

~~must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either a United States nuclear regulatory commission general or specific license prohibiting the disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the department may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or the state.~~

~~If the United States nuclear regulatory commission subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to the state will not endanger the public health, safety, welfare, or environment, the United States nuclear regulatory commission may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions provided in these criteria. If the United States nuclear regulatory commission permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.~~

~~Material and land transferred to the United States or the state in accordance with this criterion shall be transferred without cost to the United States or the state other than administrative and legal costs incurred in carrying out such transfer.~~

~~The provisions of chapter 33-10-03 respecting transfer of title and custody to land and tailings and waste shall not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for disposal of byproduct material, as defined in section 33-10-01-04, the licensee shall enter into arrangements with the United States nuclear regulatory commission as may be appropriate to assure the long-term surveillance of such lands by the United States.~~

Milling operations must be conducted so that all airborne effluent releases are reduced to levels as low as is reasonably achievable. The primary means of accomplishing this must be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are

reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. During operations and prior to closure, radiation doses from radon emissions from surface impoundments of uranium or thorium byproduct materials must be kept as low as is reasonably achievable.

Checks must be made and logged hourly of all parameters (e.g., differential pressures and scrubber water flow rates) that determine the efficiency of yellowcake stack emission control equipment operation. The licensee shall retain each log as a record for three years after the last entry in the log is made. It must be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action must be taken when performance is outside of prescribed ranges. Effluent control devices must be operative at all times during drying and packaging operations and whenever air is exhausting from the yellowcake stack. Drying and packaging operations must terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions must be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations must cease as soon as practicable. Operations may not be restarted after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All these cessations, corrective actions, and restarts must be reported to the department as indicated in criterion 8A, in writing, within ten days of the subsequent restart.

To control dusting from tailings, that portion not covered by standing liquids must be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is not exposed to wind. Consideration must be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments because this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.

Milling operations producing or involving thorium byproduct material must be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed two hundred fifty microsieverts [twenty five millirems] to the whole body, seven hundred fifty microsieverts [seventy five millirems] to the thyroid, and two hundred fifty microsieverts [twenty five millirems] to any other organ of any member of the public as a

result of exposures to the planned discharge of radioactive materials, radon-220 and its daughters excepted, to the general environment.

Uranium and thorium byproduct materials must be managed so as to conform to the applicable provisions of title 40 of the Code of Federal Regulations, part 440, "Ore Mining and Dressing Point Source Category: Effluent Limitations Guidelines and New Source Performance Standards, subpart C, Uranium, Radium, and Vanadium Ores Subcategory", as codified on January 1, 1983.

Criterion 8A--Daily inspections of tailings or waste retention systems must be conducted by a qualified engineer or scientist and documented. The licensee shall retain the documentation for each daily inspection as a record for three years after the documentation is made. The department must be immediately notified of any failure in a tailings or waste retention system that results in a release of tailings or waste into unrestricted areas, or of any unusual conditions (conditions not contemplated in the design of the retention system) that if not corrected could indicate the potential or lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

II. Financial Criteria

CRITERION 9 - Financial surety arrangements must be established by each mill operator prior to the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the mill and site and for the reclamation of any tailings or waste disposal areas. The amount of funds to be ensured by such surety arrangements must be based on department-approved cost estimates in a department-approved plan for (1) decontamination and decommissioning of mill buildings and the milling site to levels which allow unrestricted use of these areas upon decommissioning, and (2) the reclamation of tailings and waste areas in accordance with technical criteria delineated in section I of this schedule. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. The surety must also cover the payment of the charge for long-term surveillance and control required by criterion 10. In establishing specific surety arrangements, the licensee's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the department may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other federal or state agencies or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the surety which covers the decommissioning and reclamation of the mill, mill

tailings site and associated areas, and the long-term funding charge is clearly identified and committed for use in accomplishing these activities. The licensees's surety mechanism will be reviewed annually by the department to assure, that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability must be retained until final compliance with the reclamation plan is determined.

This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified period of time (e.g., five years) yet which must be automatically renewed unless the surety notifies the beneficiary (the department or the state regulatory agency) and the principal (the licensee) some reasonable time (e.g., ninety days) prior to the renewal date of their intention not to renew. In such a situation the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least sixty days for the regulatory agency to collect.

Proof of forfeiture must not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended, and must be agreed to by all parties. Financial surety arrangements generally acceptable to the department are:

(a) Surety bonds;
(b) Cash deposits;
(c) Certificates of deposits;
(d) Deposits of government securities;
(e) Irrevocable letters or lines of credit; and
(f) Combinations of the above or such other types of arrangements as may be approved by the department. However, self insurance, or any arrangement which essentially constitutes self insurance (e.g., a contract with a state or federal agency), will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

CRITERION 10 - A minimum charge of six hundred eighty thousand dollars (2001 dollars) to cover the costs of long-term surveillance

must be paid by each mill operator to the general treasury of the United States or to an appropriate state agency prior to the termination of a uranium or thorium mill license.

If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in criterion 12 (e.g., if fencing is determined to be necessary), variance in funding requirements may be specified by the department. In any case, the total charge to cover the costs of long-term surveillance must be such that, with an assumed one percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The total charge will be adjusted annually prior to actual payment to recognize inflation. The inflation rate to be used is that indicated by the change in the consumer price index published by the United States department of labor, bureau of labor statistics.

III. Site and Byproduct Material Ownership

CRITERION 11 -

A. These criteria relating to ownership of tailings and their disposal sites became effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.

B. Any uranium or thorium milling license or tailings license must contain such terms and conditions as the department determines necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.

C. Title to the byproduct material licensed under this chapter and land, including any interests therein (other than land owned by the United States or by a state) which is used for the disposal of any such byproduct material, or is essential to ensure the long term stability of such disposal site, must be transferred to the United States or the state in which such land is located, at the option of such state. In view of the fact that physical isolation must be the primary means of long-term control, and government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests (for example, mineral rights) may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either a department general or specific license prohibiting the

disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the department may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or a state.

D. If the department subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to a state will not endanger the public health, safety, welfare, or environment, the department may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions provided in these criteria. If the department permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.

E. Material and land transferred to the United States or a state in accordance with this criterion must be transferred without cost to the United States or a state other than administrative and legal costs incurred in carrying out such transfer.

F. The provisions of this chapter respecting transfer of title and custody to land and tailings and wastes do not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for the disposal of byproduct material, the licensee shall enter into arrangements with the department as may be appropriate to assure the long-term surveillance of such lands by the United States.

IV. Long-Term Site Surveillance

CRITERION 12 - The final disposition of tailings, residual radioactive material, or wastes at milling sites should be such that ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections must be conducted by the government agency responsible for long-term care of the disposal site to confirm its integrity and to determine the need, if any, for maintenance or monitoring. Results of the inspections for all the sites under the licensee's jurisdiction will be reported to the department annually within ninety days of the last site inspection in that calendar year. Any site where unusual damage or disruption is discovered during the inspection, however, will require a preliminary site inspection report to be submitted within sixty days. On the basis of a site specific evaluation, the department

may require more frequent site inspections if necessary due to the features of a particular disposal site. In this case, a preliminary inspection report is required to be submitted within sixty days following each inspection.

V. Hazardous Constituents

CRITERION 13 - Secondary ground-water protection standards required by criterion 5 of this schedule are concentration limits for individual hazardous constituents. The list of constituents in appendix I of 40 CFR part 192 identifies the constituents for which standards must be set and complied with if the specific constituent is reasonably expected to be in or derived from the byproduct material and has been detected in ground water. For purposes of this schedule, the property of gross alpha activity will be treated as if it is a hazardous constituent. Thus, when setting standards under paragraph 5B(5) of criterion 5, the department will also set a limit for gross alpha activity. The department does not consider the list imposed by appendix I of 40 CFR part 192 to be exhaustive and may determine other constituents to be hazardous on a case-by-case basis, independent of those specified by the United States environmental protection agency in appendix I of 40 CFR part 192.

History: Effective October 1, 1982; amended effective June 1, 1986; June 1, 1992; March 1, 1994.

SCHEDULE E
QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material[1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01 Non CO	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4

Radioactive Material[1]	Release fraction	Quantity (curies)
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-144m	.01	1,000
Indium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000

Radioactive Material[1]	Release fraction	Quantity (curies)
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000

Radioactive Material[1]	Release fraction	Quantity (curies)
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma . . .	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[2]	.0001	20
Combinations of radioactive materials listed above[1]	. . . .	. . . . .

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule E exceeds one.

[2] Waste packaged in type B containers does not require an emergency plan.

History: Effective March 1, 1994.

SCHEDULE F
CRITERIA RELATED TO FINANCIAL ASSURANCE AND DECOMMISSIONING
(SUBSECTION 14 OF SECTION 33-10-03-05)

Radioactive Material	Microcuries
Americium-241 (Am 241)	0.01
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100

Radioactive Material	Microcuries
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100

Radioactive Material	Microcuries
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Plutonium-239 (Pu 239)	0.01
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Radium-226 (Ra 226)	0.01
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100

Radioactive Material	Microcuries
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thorium (natural)[1]	100
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Uranium (natural)[2]	100
Uranium-233 (U 233)	0.01
Uranium-234 - Uranium-235	0.01
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100

Radioactive Material	Microcuries
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

[1] Based on alpha disintegration rate of Th-232, Th-230, and their daughter products.

[2] Based on alpha disintegration rate of U-238, U-234, and U-235.

History: Effective March 1, 1994.

SCHEDULE G
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING
(SUBSECTION 14 of SECTION 33-10-03-05)

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This schedule establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. FINANCIAL TEST

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

a. Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

b. Net working capital and tangible net worth each at least six times the current decommissioning cost estimates <u>for the total of all facilities or parts thereof</u> (or prescribed amount if a certification is used); and

c. Tangible net worth of at least $10 million; and

d. Assets located in the United States amounting to at least ninety percent of total assets or at least six times the current decommissioning cost estimates <u>for the total of all facilities</u>

or parts thereof (or prescribed amount if a certification is used).

2. The parent company must have:

   a. A current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and

   b. Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

   c. Tangible net worth of at least $10 million; and

   d. Assets located in the United States amounting to at least ninety percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the department within ninety days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within ninety days after the close of each succeeding fiscal year.

   2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the department of intent to establish alternate financial assurance as specified in the department's rules. The notice must be sent by certified mail within ninety days

after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within one hundred twenty days after the end of such fiscal year.

III. PARENT COMPANY GUARANTEE

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the department. Cancellation may not occur, however, during the one hundred twenty days beginning on the date of receipt of the notice of cancellation by both the licensee and the department, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the department's rules within ninety days after receipt by the licensee and the department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the department has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the department. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

SCHEDULE H
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING
(SUBSECTION 14 OF SECTION 33-10-03-05)

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of section II of this schedule. The terms of the self-guarantee are in section III of this schedule. This schedule establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. FINANCIAL TEST

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least ten times the total current decommissioning cost estimate <u>for the total of all facilities or parts thereof</u> (or the current amount required if certification is used) ~~for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor~~.

2. Assets located in the United States amounting to at least ninety percent of total assets or at least ten times the total current decommissioning cost estimate <u>for the total of all facilities or parts thereof</u> (or the current amount required if certification is used) ~~for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor~~.

3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities and Exchange Act of 1934 [Pub. L. 73-291; 48 Stat. 881; 15 U.S.C. 77b et seq.].

2. The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the department within ninety days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. After the initial financial test, the company must repeat passage of the test within ninety days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of section II.A. of this ~~appendix~~ schedule, the licensee must send immediate notice to the department of its intent to establish alternate financial assurance as specified in chapter 33-10-03 within one hundred twenty days of such notice.

III. COMPANY SELF-GUARANTEE

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the department. Cancellation may not occur, however, during the one hundred twenty days beginning on the date of receipt of the notice of cancellation by the department, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in chapter 33-10-03 within ninety

days following receipt by the department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

D. The licensee will promptly forward to the department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934 [Pub. L. 73-291, §13; 48 Stat. 894-895; 15 U.S.C. 78m].

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the department within twenty days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of section II.A. of this schedule.

F. The applicant or licensee must provide to the department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

SCHEDULE I
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS
(SUBSECTION 14 OF SECTION 33-10-03-05)

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of section II of this schedule. The terms of the self-guarantee are in section III of this schedule. This schedule establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. FINANCIAL TEST

A. To pass the financial test, a company must meet the following criteria:

1. Tangible net worth greater than ten million dollars, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least ninety percent of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

1. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the department within ninety days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

2. After the initial financial test, the company must repeat passage of the test within ninety days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of paragraph II.A of this schedule, the licensee must send notice to the department of intent to establish alternative financial assurance as specified in article 33-10. The notice must be sent by certified mail, return receipt requested, within ninety days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within one hundred twenty days after the end of such fiscal year.

III. COMPANY SELF-GUARANTEE

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the department. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in article 33-10 within ninety

days following receipt by the department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

D. The applicant or licensee must provide to the department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

SCHEDULE J
CRITERIA RELATING TO USE OF FINANCIAL TESTS
AND SELF-GUARANTEE FOR PROVIDING REASONABLE ASSURANCE
OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES,
UNIVERSITIES, AND HOSPITALS
(SUBSECTION 14 OF SECTION 33-10-03-05)

I. INTRODUCTION

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of section II of this schedule. The terms of the self-guarantee are in section III of this schedule. This schedule establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. FINANCIAL TEST

A. For colleges and universities, to pass the financial test, a college or university must meet either the criteria in paragraph II.A.1. or the criteria in paragraph II.A.2. of this schedule.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least fifty million dollars, or at least thirty times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test, a hospital must meet either the criteria in paragraph II.B.1. or the criteria in paragraph II.B.2. of this schedule:

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

   a. (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

   b. Long term debt divided by net fixed assets must be less than or equal to 0.67.

   c. (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

   d. Operating revenues must be at least one hundred times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the department within ninety days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test within ninety days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of section I of this schedule, the licensee must send notice to the department of its intent to establish alternative financial assurance as specified in article 33-10. The notice must be sent by certified mail, return receipt requested, within ninety days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within one hundred twenty days after the end of such fiscal year.

III. SELF-GUARANTEE

The terms of a self-guarantee which an applicant or licensee furnishes must provide that--

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the department. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in article 33-10 within ninety days following receipt by the department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

D. The applicant or licensee must provide to the department a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the department within twenty days after publication of the change by the rating service.

CHAPTER 33-10-04

STANDARDS FOR PROTECTION AGAINST RADIATION

[Repealed effective March 1, 1994]