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TITLE 13

DEPARTMENT OF FINANCIAL INSTITUTIONS

DECEMBER 2002

CHAPTER 13-03-02

13-03-02-02. Requirements for advancement of money on security of real property. No state-chartered credit union, except corporate central credit union, may advance money on security of real property until the following requirements are met:

1. The mortgage has been properly signed and recorded in the office of the ~~register of deeds of the~~ county recorder where the real property is located.

2. ~~For mortgage loans greater than twenty thousand dollars a written opinion by an attorney is obtained certifying that the mortgagor is the owner of the real property in fee simple, and indicating the order of priority of the lien established by the mortgage. For junior mortgage loans twenty thousand dollars or less, title review may be accomplished by either a written opinion by an attorney; a credit union official's written review of the public lien, mortgage, and tax lien filings; or a documented verbal opinion by an attorney supported by a title insurance company's written title search.~~ The credit union must verify that the mortgagor is the owner of the real property in fee simple and the credit union must determine the order of priority of the lien established by the mortgage.

3. ~~In lieu of a written opinion required in subsection 2, a title insurance policy equal to at least the original amount of the mortgage will be satisfactory. The policy must name the credit union as the insured.~~ For real estate loans that exceed one hundred thousand dollars, a written appraisal must be obtained by the credit union's designated appraiser. The credit union's designated appraiser must be independent of the transaction. The written appraisal must be filed with the loan documents. For real estate loans less than one hundred thousand dollars, an evaluation of the property value must be included with the loan documents; the county's annual tax statement is acceptable for this evaluation provided the loan officer indicates, in writing, agreement with the value. However, this subsection does not apply to real estate loans subject to title 12, Code of Federal Regulations, part 722,

promulgated by the national credit union administration board. For these loans, the credit union must comply with the federal requirements for transactions requiring a state-certified or licensed appraiser.

4. ~~A written appraisal has been obtained on all real estate loans. For real estate loans twenty thousand dollars or less, the county's annual tax statement is acceptable as a substitute for the written appraisal. For real estate loans more than twenty thousand dollars, a written appraisal by the credit union's designated appraiser or credit committee is acceptable. The credit union's designated appraiser must be independent of the transaction. If a credit committee is used instead of a designated appraiser, all members of the credit committee must be independent of the transaction. If the designated appraiser or credit committee member is not independent of the transaction, the credit union's board of directors must appoint someone else to replace the designated appraiser or credit committee member. In the written appraisal, the land and structures must be separately appraised based on their actual cash value. The written appraisal must be filed with the loan documents. However, this subsection does not apply to real estate loans subject to title 12, Code of Federal Regulations, part 722, promulgated by the national credit union administration board. For these loans, the credit union must comply with the federal requirements for transactions requiring a state-certified or licensed appraiser.~~

~~5.~~ Adequate fire and tornado insurance has been obtained with a mortgage clause for the benefit of the credit union in an amount equal to the amount of the outstanding liens.

~~6.~~ 5. A note for the amount of the loan has been signed by the mortgagor or mortgagors consistent with the terms of the mortgage.

~~7.~~ 6. ~~An~~ For real estate loans that exceed two hundred fifty thousand dollars, an abstract of title of the real property ~~for first real estate mortgages~~ must be furnished to the credit union, at the expense of the borrower, unless an abstract of title is not prepared and, in that case, a title insurance policy is required. Within ~~ninety~~ forty-five days after the advancement of funds, the abstract of title, if prepared, must be updated to include the mortgage. ~~After one year from the date of the first real estate mortgage, the credit union may return the abstract to the mortgagor.~~

History: Amended effective May 1, 1982; November 1, 1985; October 1, 1994; August 1, 1998; December 1, 2002.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-06-06

13-03-02-03. Length of term - Amortization - Limitation on amount of percent of appraised value.

1. All amortized loans secured by real property shall be limited to a term of thirty years, and an amount of ~~eighty~~ ninety percent of the appraised value of the real estate being mortgaged as security for the loan.

2. ~~All unamortized loans secured by real property shall conform to either subdivision a or b.~~ When a loan specified in subsection 1 is insured by private mortgage insurance, the permissible amount shall not exceed the amount that is covered by the insurance.

   ~~a. Ninety percent of appraised value of the real estate being mortgaged and a term of one year.~~

   ~~b. Fifty percent of appraised value of the real estate being mortgaged and a term of five years.~~

3. When a loan specified in subsection 1 is insured by private mortgage insurance, the permissible amount shall be extended to no more than ninety-five percent.

History: Amended effective June 1, 1979; May 1, 1981; December 1, 2002.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-06-06

APRIL 2003

CHAPTER 13-02-14

13-02-14-01. Definitions. "~~Executive officer~~ Key person" means the chairman of the board, the president, each vice president, the cashier, the secretary, ~~and~~ the treasurer, or any other employee or director of a bank or bank holding company whose absence for an extended period of time would result in a significant loss of net income for the bank, unless such ~~officer~~ key person is excluded, by resolution of the board of directors or by the bylaws of the bank or bank holding company, from participation, other than in the capacity of a director, in ~~major~~ policymaking functions of the bank or bank holding company, and the ~~officer~~ key person does not actually participate in ~~major~~ policymaking functions of the bank or bank holding company.

History: Effective April 1, 1992; amended effective April 1, 2003.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-03-02

13-02-14-02. Authority to purchase life insurance. Banks may purchase and hold an interest in individual or group life insurance policies on the life of its ~~executive officers~~ key persons, directors, and borrowers, and may purchase life insurance in connection with ~~employee~~ compensation and benefit plans for its officers, directors, and employees, subject to the limitations in this chapter. The bank is not authorized to purchase policies if the board's basis for its insurable interest is primarily based upon the ~~executive officer~~ employee or director being a shareholder of the bank or bank holding company. Funding for the payment of ~~employee~~ compensation and benefit plans may be made or split in a joint manner between the bank, employee, director, or bank holding company as in "split dollar" or other insurance plans. ~~Banks may purchase individual or group policies in connection with deferred compensation agreements entered into with its officers and employees. Banks may purchase policies on directors to fund a deferred directors fees program.~~

History: Effective April 1, 1992; amended effective April 1, 2003.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-03-02

13-02-14-03. Limitations.

1. A bank is not authorized to purchase life insurance policies for the bank's own account as an investment.

2. Except as provided in subsections 3 and 4, the bank's purchase of life insurance policies underwritten by one company cannot exceed fifteen percent of the bank's tier 1 capital.

3. The bank's purchase of any life insurance policy underwritten by one company ~~on an executive officer~~ for key person purposes cannot exceed twenty-five percent of the bank's capital stock and surplus as measured by the policy's cash surrender value.

~~3.~~ 4. The bank's purchase of any life insurance policy underwritten by one company on a director cannot exceed ten percent of the bank's capital stock and surplus as measured by the policy's cash surrender value.

~~4.~~ 5. ~~A bank is not allowed to commit an amount toward the purchase of life insurance policies, as measured by the cash surrender value, that is more than~~ The bank's purchase of life insurance policies from all carriers in the aggregate cannot exceed twenty-five percent of the bank's tier 1 capital ~~stock, surplus, and undivided profits~~. This limit shall apply to the initial purchase of life insurance policies as measured by the amount of premium and to subsequent purchases as measured by the sum of the cash surrender value of earlier purchases plus the amount of premium committed toward subsequent purchases.

~~5.~~ 6. The bank is not authorized to purchase life insurance policies for the primary purpose of providing estate planning ~~purposes~~ benefits for bank insiders unless it is part of a reasonable compensation package.

~~6.~~ 7. The bank's authority to hold life insurance on any ~~executive officer~~ key person ceases when the ~~executive officer~~ key person is no longer employed by the bank, or no longer meets the definition of ~~an executive officer~~ key person.

~~7.~~ 8. The bank's authority to hold life insurance on a director ceases when that director is no longer a member of the board of directors and there is no liability or obligation under director compensation and benefit plans.

~~8.~~ 9. The bank's authority to purchase life insurance on borrowers is subject to the following:

   a. The face value of the life insurance policy cannot exceed the borrower's obligation to the bank.

   b. The bank has not charged off nor is expected to charge off the borrower's obligation.

~~9.~~ 10. In purchasing life insurance in connection with employee compensation and benefit plans, the bank ~~is not authorized to hold the policies if no liability exists under the deferred compensation plans unless specifically approved by the state banking board~~ may retain the policies after the insured's employment is terminated, provided the bank has continuing liabilities or obligations under such plans.

History: Effective April 1, 1992; amended effective April 1, 2003.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-03-02

13-02-14-05. Documentation.

1. In purchasing life insurance for ~~executive officers or directors~~ key person purposes, the bank's board of directors must adequately document in its minutes the basis for its insurable interest and the basis for the amount of insurance. The bank's board of directors must also document in its minutes the basis for determining how that ~~officer~~ employee or director meets the definition of ~~an executive officer~~ a key person.

2. In purchasing life insurance in connection with ~~employee~~ compensation and benefit plans ~~and deferred directors fees programs~~ for employees, officers, and directors, the bank's board of directors must approve and document such plans or programs including the reasonableness of the plans or programs.

History: Effective April 1, 1992; amended effective April 1, 2003.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-03-02

13-02-14-06. Waiver. The state banking board or commissioner may waive any limitation or restriction in this chapter ~~as to policies purchased before the effective date of this chapter. The state banking board may permit the bank to continue to hold a life insurance policy on an employee covered by a compensation and benefit plan who terminates or retires from employment of the bank~~.

History: Effective April 1, 1992; amended effective April 1, 2003.
General Authority: NDCC 6-01-04
Law Implemented: NDCC 6-03-02, 6-03-38

TITLE 33

STATE DEPARTMENT OF HEALTH

MARCH 2003

CHAPTER 33-06-01

33-06-01-01. Reportable conditions. All reports and information concerning reportable conditions are confidential and not open to inspection. The following designated reportable conditions must be reported to the state department of health by the persons designated in chapter 33-06-02. If any reportable condition is designated by an asterisk, an appropriate sample or isolate must be submitted to the division of microbiology (public health laboratory) in addition to the required report.

1. Anthrax*.
2. Botulism*.
3. Brucellosis*.
4. Campylobacter enteritis*.
5. Cancer, all invasive and in situ carcinomas (except basal and squamous cell skin carcinomas or carcinoma in situ of the cervix uteri).
6. Chickenpox (varicella).
7. Chlamydial infections.
8. Cholera*.
9. Clostridium perfringens intoxication.
10. Creutzfeldt-Jakob disease.
11. Cryptosporidiosis.

~~10.~~ 12. Diphtheria*.

~~11.~~ 13. Encephalitis (arboviral encephalitides only).

~~12.~~ 14. Enteric E. coli infection (includes E. coli 0157:H7 and infections caused by other enterohemorrhagic, enteropathogenic, or enteroinvasive E. coli)*.

~~13.~~ 15. Enterococcus, vancomycin resistant (VRE)*.

~~14.~~ 16. Foodborne or waterborne outbreaks.

~~15.~~ 17. Giardiasis.

18. Glanders*.

~~16.~~ 19. Gonorrhea.

~~17.~~ 20. Hantavirus*.

~~18.~~ 21. Haemophilus influenzae infection (invasive infection with haemophilus influenzae isolated from blood, cerebral spinal fluid, or other normal sterile site)*.

~~19.~~ 22. Hemolytic uremic syndrome.

~~20.~~ 23. Hepatitis (specify type).

~~21.~~ 24. Human immunodeficiency virus (HIV) infection, including acquired immunodeficiency syndrome (AIDS)*. (Any positive HIV test result.)

~~22.~~ 25. Human immunodeficiency virus (HIV) nucleic acid test result (detectable or nondetectable).

~~23.~~ 26. Influenza.

~~24.~~ 27. Lead blood level greater than or equal to 10 ug/dl.

~~25.~~ 28. Legionellosis.

~~26.~~ 29. Listeriosis*.

~~27.~~ 30. Lyme disease.

~~28.~~ 31. Malaria*.

~~29.~~ 32. Measles (rubeola)*.

33. Melioidosis*.

~~30.~~ 34. Meningitis, bacterial (all bacterial species isolated from cerebrospinal fluid)*.

~~31.~~ 35. Meningococcal disease (invasive infection with neisseria meningitidis isolated from blood, cerebral spinal fluid, or other normal sterile site)*.

~~32.~~ 36. Mumps.

37. Nipah viral infections.

~~33.~~ 38. Nosocomial outbreaks in institutions.

~~34.~~ 39. Pertussis*.

~~35.~~ 40. Plague*.

~~36.~~ 41. Poliomyelitis*.

42. Psittacosis.

~~37.~~ 43. Q fever*.

~~38.~~ 44. Rabies (animal or human*).

~~39.~~ 45. Rocky Mountain spotted fever.

~~40.~~ 46. Rubella*.

~~41.~~ 47. Salmonellosis*.

~~42.~~ 48. Scabies outbreaks in institutions.

~~43.~~ 49. Shigellosis*.

50. Smallpox.

~~44.~~ 51. Staphylococcus aureus, methicillin resistant (MRSA), all sites. All isolates from blood, cerebral spinal fluid, or other normal sterile site must be forwarded to the North Dakota public health laboratory.

~~45.~~ 52. Staphylococcus aureus, vancomycin resistant (VRSA) (any staphylococcus aureus isolate demonstrating intermediate or greater resistance to vancomycin of MIC greater than or equal to 8 ug/ml)*.

53. Staphylococcus enterotoxin B intoxication.

~~46.~~ 54. Streptococcal infections (invasive infection of streptococcus group A or B or streptococcus pneumoniae isolated from blood, cerebral spinal fluid, or other normal sterile site)*.

~~47.~~ 55. Syphilis.

~~48.~~ 56. Tetanus.

57. Tickborne encephalitis viruses*.

58. Tickborne hemorrhagic fevers.

~~49.~~ 59. Toxic-shock syndrome*.

~~50.~~ 60. Trichinosis.

~~51.~~ 61. Tuberculosis (tuberculosis disease caused by mycobacterium tuberculosis or mycobacterium bovis)*.

~~52.~~ 62. Tularemia*.

~~53.~~ 63. Tumors of the central nervous system.

~~54.~~ 64. Typhoid fever*.

~~55.~~ 65. Unexplained critical illness or death in an otherwise healthy person.

~~56.~~ 66. Unusual cluster of severe or unexplained illnesses or deaths.

67. Viral hemorrhagic fevers.

~~57.~~ 68. Weapons of mass destruction suspected event.

69. Yellow fever*.

History: Amended effective May 1, 1984; December 1, 1986; January 1, 1988; January 1, 1989; October 1, 1990; January 1, 1991; February 1, 1992; May 1, 1994; January 1, 1995; July 1, 1996; February 1, 2000; August 1, 2002; March 1, 2003.
General Authority: NDCC 23-07-01
Law Implemented: NDCC 23-07-01

CHAPTER 33-06-16

33-06-16-01. ~~Research and testing materials~~ Definitions. ~~Information and testing materials generated by the neonatal metabolic screening program under North Dakota Century Code chapter 25-17 are strictly confidential information subject to North Dakota Century Code section 23-01-15.~~ As used in this chapter:

1. ~~Access to information or testing materials may be obtained only as follows:~~ "Diagnostic test" means a test that is used to establish a definitive diagnosis of some condition in an affected newborn.

   ~~a. Information may be released for statistical purposes in a manner such that no individual person can be identified.~~

   ~~b. Information may be released to the individual tested, that person's parent or guardian, or that person's physician or dietitian.~~

   ~~c. Information and testing materials may be released to a person engaged in a bona fide research project concerning medical, psychological, or sociological issues provided all of the following conditions are met:~~

      ~~(1) The research project must be sponsored by a public or private college or university; a governmental entity; a nonprofit medical, sociological, or psychological association; or the pharmaceutical industry.~~

      ~~(2) The research project must be reviewed and approved pursuant to policies and procedures pertaining to research utilizing human subjects by the institutional review board or equivalent panel of the institution or entity where the research is being done or which is sponsoring the research.~~

      ~~(3) Identifying information may not appear in any report, summation, thesis, or other document arising out of the research project.~~

      ~~(4) Identifying information may not be provided to a person engaged in a bona fide research project until that person has submitted a written proposal explaining and justifying the need to examine such information which is satisfactory to the state health officer. The state health officer may require the research to be approved by the university of North Dakota institutional review board.~~

      ~~(5) All documents or testing materials received by the researcher and all documents containing identifying information made by or on behalf of the researcher, by whatever means, including~~

~~hard copies, typewritten or handwritten copies, photocopies, facsimiles, or electronic or electromagnetic recording or imaging, must be returned to the department on or before a date that the state health officer shall set.~~

~~(6) The researcher shall submit a written plan explaining how all identifying information in the researcher's possession will be kept secure, to the satisfaction of the state health officer who shall obtain written assurance that the plan will be implemented.~~

~~(7) The researcher shall agree to provide the state health officer a copy of any report, summation, thesis, or other document arising out of the research project for departmental review of compliance with this section before providing it to the publisher.~~

~~(8) The researcher shall consent in writing to the use and reproduction of the document by the department.~~

~~(9) The researcher shall agree in writing to pay all costs of the state health officer or the department incurred in providing access to testing materials or other information, including copy or search services.~~

~~d. Release may be made as otherwise provided by statute.~~

2. ~~Retention and destruction of information and testing materials.~~ "Newborn screening system" means the routine testing of newborn infants for congenital conditions by analysis of a dried blood specimen through laboratory procedures that identify infants with an increased risk for specified diseases and conditions, and that justify followup actions and diagnostic tests or procedures.

~~a. Information and testing materials provided to the university of North Dakota school of medicine may be retained indefinitely or destroyed according to this subsection.~~

~~b. Information and testing materials may be destroyed by any available means that preserves individual confidentiality and, for the testing materials, complies with any applicable standards for destruction of human blood samples.~~

~~c. Information and testing materials may be destroyed based upon the following schedule:~~

~~(1) Information and testing materials created less than ten years before the present date may be destroyed only with the state health officer's prior written approval.~~

~~(2) After ten years, information and testing materials may be destroyed without prior approval.~~

3. ~~Definitions. For purposes of this section:~~ "Program" means the North Dakota newborn screening program in the division of maternal and child health in the state department of health.

   ~~a. "Disease" includes physical, genetic, or environmental conditions; psychological or mental conditions; and addictions.~~

   ~~b. "Identifying information" includes any information that, alone or in conjunction with information available to the public, could identify a particular person as having or potentially having been exposed to a disease, having or potentially having a disease, or having or potentially having a predisposition for disease.~~

4. "Protected health information" has the meaning set forth in North Dakota Century Code section 23-01.3-01.

5. "Tandem mass spectrometry" is a laboratory technology that uses a machine consisting of two mass spectrometers joined by a fragmentation chamber. Tandem mass spectrometry technology allows the identification of an array of metabolic conditions, such as amino acid, fatty acid, and organic acid disorders, from a single dried blood spot.

History: Effective December 1, 1996; amended effective March 1, 2003.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

33-06-16-02. Testing of newborns. Under the newborn screening system, except as authorized by section 33-06-16-04, each newborn infant born in this state shall be tested for the metabolic diseases phenylketonuria, hypothyroidism, galactosemia, congenital adrenal hyperplasia, biotinidase deficiency, sickle cell disease, and other hemoglobinopathies, and any other disease that can be identified through tandem mass spectrometry that is designated on the department's test schedule with a designated laboratory engaged to perform this testing on behalf of the program.

History: Effective March 1, 2003.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

33-06-16-03. Physician responsibility.

1. The physician or other birth attendant shall order that:

a. A specimen of blood be collected from a newborn in accordance with directions supplied by the laboratory designated by the state department of health and the program; and

b. The specimen be sent to that laboratory.

2. If a patient, who has a condition for which the program conducts a screening test, but which has been detected by another mechanism or by an out-of-state screening program, the patient's physician shall within thirty days of becoming aware of the patient's condition, notify the program of the patient's name, parent's name if the patient is under eighteen years of age, date of birth, address, and condition.

History: Effective March 1, 2003.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

33-06-16-04. Refusal of testing.

1. If the parents or guardians refuse to have their infant receive newborn screening testing as authorized by North Dakota Century Code section 25-17-04, that refusal shall be documented by a written statement signed by the parents or guardians.

2. The original refusal statement shall become a part of the infant's medical record and a copy of the statement shall be submitted to the program.

History: Effective March 1, 2003.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

33-06-16-05. Research and testing materials. Information and testing materials generated by the newborn screening program under North Dakota Century Code chapter 25-17 are strictly confidential information subject to North Dakota Century Code chapter 23-01.3 and section 23-01-15.

1. Access to information or testing materials may be obtained only as follows:

a. Information may be disclosed for statistical purposes in a manner such that no individual person can be identified.

b. Information may be disclosed to the individual tested, that person's parent or guardian, or that person's physician or dietitian, or to the children's special health services program of the department of human services for purposes of coordination of services and provision of medical and low-protein modified foods.

c. Information and testing materials may be disclosed to a person engaged in a bona fide research project concerning medical, psychological, or sociological issues provided all of the following conditions are met:

(1) The research project must be sponsored by a public or private college or university; a governmental entity; a nonprofit medical, sociological, or psychological association; or the pharmaceutical industry.

(2) The research project must be reviewed and approved pursuant to policies and procedures pertaining to research utilizing human subjects by the institutional review board or equivalent panel of the institution or entity where the research is being done or which is sponsoring the research.

(3) Protected health information may not appear in any report, summation, thesis, or other document arising out of the research project.

(4) Protected health information may not be provided to a person engaged in a bona fide research project until that person has submitted a written proposal explaining and justifying the need to examine such information which is satisfactory to the state health officer. The state health officer may require the research to be approved by the university of North Dakota institutional review board.

(5) All documents or testing materials received by the researcher and all documents containing protected health information made by or on behalf of the researcher, by whatever means, including hard copies, typewritten or handwritten copies, photocopies, facsimiles, or electronic or electromagnetic recording or imaging, must be returned to the department on or before a date that the state health officer shall set.

(6) The researcher shall submit a written plan explaining how all protected health information in the researcher's possession will be kept secure to the satisfaction of the state health officer who shall obtain written assurance that the plan will be implemented.

(7) The researcher shall agree to provide the state health officer a copy of any report, summation, thesis, or other document arising out of the research project for departmental review of compliance with this section before providing it to the publisher.

(8) The researcher shall consent in writing to the use and reproduction of the document by the department.

(9) The researcher shall agree in writing to pay all costs of the state health officer or the department incurred in providing access to testing materials or other information, including copy or research services.

d. Disclosure may be made as otherwise provided by statute.

2. Retention and destruction of information and testing materials.

a. Information and testing materials provided to the university of North Dakota school of medicine and health sciences may be retained indefinitely or destroyed according to this subsection.

b. Information and testing materials may be destroyed by any available means that preserves individual confidentiality and, for the testing materials, complies with any applicable standards for destruction of human blood samples.

c. Information and testing materials may be destroyed based upon the following schedule:

(1) Information and testing materials created less than ten years before the present date may be destroyed only with the state health officer's prior written approval.

(2) After ten years, information and testing materials may be destroyed without prior approval.

History: Effective March 1, 2003.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

CHAPTER 33-10-01

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) 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 the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

13. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material~~.~~; and ~~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 ($H_{E,50} = \Sigma W_T H_{T,50}$).

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

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

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

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 ($H_E = \Sigma W_T H_T$).

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/cm^2). This assumes a tissue density of one gram per cubic centimeter.~~

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

~~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 from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one hundred millirems [one millisievert] in one hour at thirty centimeters from any source of radiation or from any surface that the radiation penetrates.

~~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, incorporated.

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 radiation or to radioactive material from licensed, unlicensed, registered, and unregistered 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~~ materials and released in accordance with ~~subsection 12 of~~ section ~~33-10-07-05~~ 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~~ a state ~~to compound and dispense drugs, prescriptions, and poisons~~ 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 purposes 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.

83. "Public dose" means the dose received by a member of the public from ~~sources of~~ exposure to radiation ~~from a licensed or registered operation~~ or radioactive material released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with ~~subsection 12 of~~ section ~~33-10-07-05~~ 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 exposure is the coulomb per kilogram (C/kg). (See section 33-10-01-14 units of radiation exposure, dose, and activity for the special unit equivalent "roentgen" (R).)

~~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 requirements.

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

~~101.~~ "Residual radioactivity" means radioactivity in structures, materials,
102. 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.~~ "Restricted area" means an area, access to which is limited by the
103. licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. "Restricted area" does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

~~103.~~ "Roentgen" (R) means the special unit of exposure. One roentgen
104. equals two hundred fifty-eight millionths of a coulomb per kilogram of air. (See "exposure")

~~104.~~ "Sealed source" means radioactive material that is permanently bonded
105. 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.~~ "Shallow dose equivalent" (H_s), which applies to the external exposure
106. 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.~~ "SI" means the abbreviation for the international system of units.
107.

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

~~108.~~ "Site area emergency" means events may occur, are in progress, or
109. 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.~~ "Special nuclear material in quantities not sufficient to form a critical
116. 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.~~ "Surface contaminated object" (SCO) means a solid object that is not
117. 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 ~~becquerels~~ 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 three hundred cm^2) does not exceed forty thousand becquerels per square centimeter (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or four thousand

becquerel per square centimeter (0.1 microcurie/cm^2) for all other alpha emitters.

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

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

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

(3) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over three hundred square centimeters (or the area of the surface if less than three hundred cm^2) does not exceed eight hundred thousand becquerels per square centimeter (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or eighty thousand becquerels per square 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.~~ "Total organ dose equivalent" (TODE) means the sum of the deep dose
122. 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.~~ "United States department of energy" means the department of energy
123. established by Public Law No. 95-91 [91 Stat. 565; 42 U.S.C. 7101 et seq.] to the extent that the department exercises functions formerly vested in the United States atomic energy commission, its chairman, members, officers, and components and transferred to the United States energy research and development administration and to the administrators thereof pursuant to sections 104(b), (c), and (d) of the Energy Reorganization Act of 1974 [Pub. L. 93-438; 88 Stat. 1237; 42 U.S.C. 5814, effective January 19, 1975] and transferred to the secretary of energy pursuant to subsection 301(a) of the Department of Energy Organization Act [Pub. L. 95-91; 91 Stat. 577-578; 42 U.S.C. 7151, effective October 1, 1977].

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

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

~~125.~~ "Uranium" natural, depleted, enriched:
126.

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

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

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

127. "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.

~~126.~~ 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; March 1, 2003.
General Authority: NDCC 28-32-02, 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

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Division of ~~Environmental Engineering~~ Air Quality
1200 Missouri Avenue, Room 304
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Bismarck, ~~North Dakota 58506-5520~~ ND 58504

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Telephone (701)328-5188
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24-hour emergency in-state 800-472-2121; out-of-state (701)328-9921

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

CHAPTER 33-10-03

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~~ 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 1, 1986; June 1, 1992; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-23.1-04

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 rates:

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

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

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

[8] 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 one-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 megabecquerel [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 ten micrograys [1 millirad] per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

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

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

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

[3] For americium-241, 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, 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 thirty-seven kilobecquerels [1 microcurie] of 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.

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

33-10-03-04. General licenses.

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

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

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

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

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

e. Depleted uranium in industrial products and devices.

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

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

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

[1] Name and address of the registrant.

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

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

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

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

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

(b) May not abandon such depleted uranium.

(c) Shall transfer or dispose of such depleted uranium only by transfer in accordance with subsection 12 of section 33-10-03-05. In the case where the transferee

receives the depleted uranium pursuant to the general license established by paragraph 1, the transferor shall furnish the transferee a copy of this article and a copy of form SFN 16092. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the United States nuclear regulatory commission's or agreement state's regulation equivalent to paragraph 1, the transferor shall furnish the transferee a copy of this article and a copy of form SFN 16092 accompanied by a note explaining that use of the product or device is regulated by the United States nuclear regulatory commission or agreement state under requirements substantially the same as those in this article.

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

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

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

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

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

(1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources,

radioactive material consisting of a total of not more than 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 a~~ of polonium-210 per device or a total of not more than one and eighty-five hundredths gigobecquerels [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 or initially transferred 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~~ an equivalent specific license issued by the United States nuclear regulatory commission, an agreement state, or a licensing state ~~which authorizes distribution of devices to persons generally licensed by the nuclear regulatory commission, an agreement state, or a licensing state. (Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.)~~

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.

(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 ~~tests~~ a test 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 ~~tests~~ a test 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 which are~~ Each record that is 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~~, or~~. 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 ~~and, within thirty days, furnish to the department a~~ or as otherwise approved by the department. 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) ~~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.~~ Shall not export the device containing radioactive material except in accordance with 10 CFR part 110.

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

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

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

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

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

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

(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, 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 telephone 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 [10 millicuries] of cesium-137, three thousand seven hundred kilobecquerels [100 microcuries] of strontium-90, thirty-seven megabecquerels [1 millicurie] of cobalt-60, or thirty-seven megabecquerels [1 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.

[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 manufacture (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 devices 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 devices

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 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 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 nonagreement 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 any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.53 of the regulations of the United States nuclear regulatory commission.

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

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

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

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

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

e. Calibration and reference sources.

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

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

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

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

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

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

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

(a) Shall not possess at any one time, at any one location of storage or use, more than 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 any agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

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

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

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

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

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

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

3. **Bankruptcy.** Each general licensee that is required to register by subparagraph m of paragraph 3 of subdivision b of subsection 2 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; March 1, 2003.
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~~ subsection 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~~ subdivision the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

g. Financial surety arrangements for site reclamation.

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

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

(b) Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement since this provides no additional assurance

other than that which already exists through license requirements.

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

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

(a) Major processors.

(b) Waste handling licensees.

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

(d) Source material milling operations.

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

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

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

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

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

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

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

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

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

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

(1) Waste handling licensees.

(2) Source material milling licensees.

i. Continued surveillance requirements for source material mills.

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

(2) A minimum charge of ~~two~~ 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 of section ~~33-10-05-06~~ 33-10-05-05.

      (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 for possible leakage and contamination and submits to the department a description of such procedures including~~ If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of each person authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

(a) ~~Instrumentation~~ Instruments to be used~~.~~;

(b) ~~Method~~ Methods of performing ~~tests.~~ the analysis; and

(c) Pertinent experience of the ~~individual~~ person who will ~~perform~~ analyze the ~~test~~ wipe samples.

(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 individuals 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 persons 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 locations 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 evaluation of proposed uses prepared in accordance with item 2 of this subparagraph prior to use of the radioactive material.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Receive, acquire, own, possess, use, or transfer devices containing 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 naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors to be distributed to persons exempt under paragraph 3 of subdivision c of subsection 2 of section 33-10-03-02 will be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device may not exceed three and seven-tenths kilobecquerels [0.1 microcurie].

d. ~~Licensing the manufacture and distribution of~~ Radioactive material contained in devices ~~to persons generally licensed~~ 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 ~~of this section~~.

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

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

[2] Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it

is unlikely that any person will receive in any period of one calendar year a dose in excess of ten percent of the 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	15 rems [150 millisieverts]
[b]	Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	200 rems [2 sieverts]
[c]	Other organs	50 rems [500 millisieverts]

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

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

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

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

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

license or the equivalent and the regulations of the United States nuclear regulatory commission or a state with which the United States nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. (The model, serial number, and name of manufacturer or ~~distributor~~ 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 test.

(g) Maximum pressure withstood during prototype tests.

(h) Maximum quantity of contained radioactive material.

(i) Radiotoxicity of contained radioactive material.

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

(3) In the event the applicant desires that the general licensee under subdivision b of subsection 2 of section 33-10-03-04, or under equivalent regulations of the United States nuclear regulatory commission, an agreement state, or a licensing

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

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

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

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

~~(c) Report to the department all transfers of such devices to persons for use under the general license in subdivision b of subsection 2 of section 33-10-03-04. Such report~~

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

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

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

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

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

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

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

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

(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 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 subparagraph b, c, d, or m of paragraph 3 of subdivision b does 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 this subdivision 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 telephone 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.

(e) If a notification of bankruptcy has been made under subsection 3 of section 33-10-03-04 or subsection 7 or the license is to be terminated, each person licensed under this subdivision 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.

(5) Material transfer reports and records. Each person licensed under this subdivision 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 telephone 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 persons.

[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 telephone 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 persons.

[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.

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 [0.5 microcurie] of iodine-129 and one and eighty-five hundredths kilobecquerels [0.5 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 this article and a general license of a licensing state.

_____

Name of manufacturer

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

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

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

(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 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~~ 33-10-07.1-02, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in ~~paragraphs 2~~ subparagraphs 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~~ 33-10-07.1-16.

(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.~~ 33-10-07.1-02;

[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 e 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~~ 33-10-07.1-02, 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 States nuclear regulatory commission under 10 Code of Federal Regulations part 32.

(e) Shall provide to the department a copy of each individual's certification by the board of pharmaceutical specialties, the United States nuclear regulatory commission or agreement state 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 thirty days after the date that the licensee allows, pursuant to items 1 and 3 of subparagraph b, the individual to work as an authorized nuclear pharmacist.

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

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry ~~dependents~~ 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 thirty-seven kilobecquerels [1 microcurie] of 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 2, provided that the requirements of subdivisions a and c of subsection 2 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 b of subsection 2;

[3] The applicant provides evidence that each capsule contains thirty-seven kilobecquerels [1 microcurie] of 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 this subdivision is subject to the following conditions:

[1] The immediate container of the capsules 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, 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".

(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~~ 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~~ sections 33-10-07.1-47, 33-10-07.1-57, and 33-10-07.1-59 will be approved if:

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

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

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

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

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

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

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

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

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

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

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

(f) Maximum temperature withstood during prototype tests.

(g) Maximum pressure withstood during prototype tests.

(h) Maximum quantity of contained radioactive material.

(i) Radiotoxicity of contained radioactive material.

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

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

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

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

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

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

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

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

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

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

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

(b) Label or mark each unit to:

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

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

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

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

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

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

(f) [1] Report to the United States nuclear regulatory commission all transfers of industrial products

or devices to persons for use under the United States nuclear regulatory commission general license in 10 CFR 40.25.

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

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

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

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

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

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

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

(a) Description of the proposed project or action.

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

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

(d) Environmental effects of accidents.

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

(f) Site and project alternatives.

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

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

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

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

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

mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time, e.g., five years, which must be automatically renewed unless the surety agent notifies the beneficiary (the state regulatory agency) and the principal (the licensee) some reasonable time, e.g., ninety days, prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least sixty days for the regulatory agency to collect.

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

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

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

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

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

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

[2] Any unusual conditions (conditions not contemplated in the design of the retention system) which if not corrected could lead to

failure of the system and result in a release of tailings or waste into unrestricted areas.

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

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

(b) A minimum charge of ~~two~~ 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 this chapter

~~33-10-03~~. Each application must clearly demonstrate how the requirements and objectives set forth in Schedule D of this chapter 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 approved plan without department approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the department and to affected onsite response organizations within six months after the change is made. Proposed changes that decrease or potentially decrease the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the department.

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

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

(1) The licensee;

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

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

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

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

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

renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

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

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

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

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

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

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

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

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

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

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

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

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

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

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 with present funds set aside for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(f) For decommissioning plans calling for completion of decommissioning later than twenty-four months after plan approval, the plan must include a justification for the delay based on the criteria in subdivision 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 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 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 33-10-04.1-18.

(4) Records required by ~~subsection 14 of section 33-10-03-05 and sections 33-10-04.1-14 and 33-10-04.1-15~~ 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 any order of the department.

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

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

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

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

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

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by subdivision d using one of the methods described in subdivision f. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but 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 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; March 1, 2003.
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 except in areas of federal jurisdiction provided that:

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

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

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

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

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

c. The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the United States nuclear regulatory commission or an agreement

state, or of any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

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

   a. Subject to this article, any person who holds a specific license from a licensing state, and issued by the department having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty days in ~~any calendar year~~ 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~~ 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 may not transfer or dispose of radioactive material possessed or used under the general

license provided in subdivision a except by transfer to a person:

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

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

(6) The out-of-state licensee shall submit an annual reciprocity fee, as described in chapter 33-10-11, at the time of ~~written notification~~ 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 section 33-10-03-09 or 33-10-13-22.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; May 1, 1998; March 1, 2003.
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

33-10-03-08. 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.

History: Effective March 1, 2003.
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

33-10-03-09. 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.

History: Effective March 1, 2003.
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

33-10-03-10. 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.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04, 23-20.1-04.5
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.5

SCHEDULE A
EXEMPT CONCENTRATIONS

Element (Atomic Number)	Radionuclide	Column I Gas Concentration µCi/ml[1/]	Column II Liquid and Solid Concentration µCi/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		$4x10^{-4}$

Element (Atomic Number)	Radionuclide	Column I Gas Concentration µCi/ml[1/]	Column II Liquid and Solid Concentration µCi/ml[2/]
Erbium (68)	Er-169		$9x10^{-4}$
	Er-171		$1x10^{-3}$
Europium (63)	Eu-152		$6x10^{-4}$
	($T_{\frac{1}{2}}$=9.2h)		
	Eu-155		$2x10^{-3}$
Fluorine (9)	F-18	$2x10^{-6}$	$8x10^{-3}$
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		$1x10^{-3}$

Element (Atomic Number)	Radionuclide	Column I Gas Concentration µCi/ml[1/]	Column II Liquid and Solid Concentration µCi/ml[2/]
Mercury (80)	Hg-197m		$2x10^{-3}$
	Hg-197m		$3x10^{-3}$
	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	Nb-95		$1x10^{-3}$
(Columbium) (41)	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		$2x10^{-4}$
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		$8x10^{-4}$

Element (Atomic Number)	Radionuclide	Column I Gas Concentration µCi/ml[1/]	Column II Liquid and Solid Concentration µCi/ml[2/]
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		$3x10^{-4}$
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.		$1x10^{-10}$	$1x10^{-6}$

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Schedule A, the activity stated is that of the parent radiounclide 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: Concentration of Radionuclide A in Product + Exempt concentration of Radionuclide A

Concentration of Radionuclide B in Product < 1
Exempt concentration of Radionuclide B

Note 3: To convert µCi/ml to SI units of megabecquerels per liter, multiply the above values by 37.

Example: Zirconium (40) Zr-97 ($2x10^{-4}$ µCi/ml multiplied by 37 is equivalent to $74x10^{-4}$ megabecquerels per liter).

[1/] Values are given in column I only for those materials normally used as gases.

[2/] µCi/g for solids.

History: Amended effective June 1, 1992; May 1, 1998; March 1, 2003.

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
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

Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-103 (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
Sulfur-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
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
Tttrium-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; March 1, 2003.

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
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 yr)	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
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
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
Sulfur-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
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).

History: Amended effective June 1, 1992; May 1, 1998; March 1, 2003.

SCHEDULE D
CRITERIA RELATING TO THE OPERATION OF URANIUM MILLS AND THE DISPOSITION OF 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 I of subsection 5 of section 33-10-03-05, 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.

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, 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 amendability of the disposal system to accommodate increased capacities without degradation in long-term stability and other performance factors shall be evaluated.

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 manmade 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 manmade 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, windblown 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, manmade 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:

- Remoteness from populated areas;

- Hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from ground water sources; and

- Potential 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 function of both site 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 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 in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote aboveground extraction operations shall 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 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 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 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; 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, 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 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 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 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 department will consider relaxing this requirement for extremely gentle slopes such as those which may exist on the tope 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 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 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 - 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 CFR 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 standards 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 down gradient 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; and

[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; and

[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 -

(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 and 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 nonsoil 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.

[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 at 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.

(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 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 postclosure 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 - 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.

Criterion 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 - 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 [25 millirems] to the whole body, seven hundred fifty microsieverts [75 millirems] to the thyroid, and two hundred fifty microsieverts [75 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 licensee'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; March 1, 2003.

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	50,000
	Non CO	
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
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000

Radioactive Material[1]	Release Fraction	Quantity (Curies)
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
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

Radioactive Material[1]	Release Fraction	Quantity (Curies)
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
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

Radioactive Material[1]	Release Fraction	Quantity (Curies)
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; amended effective March 1, 2003.

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

Radioactive Material	Microcuries
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
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

Radioactive Material	Microcuries
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

Radioactive Material	Microcuries
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
Plonium-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-193m (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

Radioactive Material	Microcuries
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
Sulfur-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
Tellurim-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

Radioactive Material	Microcuries
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
Vanvadium-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 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; amended effective March 1, 2003.

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;

   b. Net working capital and 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);

   c. Tangible net worth of at least ten million dollars; 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 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;

   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);

c. Tangible net worth of at least ten million dollars; 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 for the total of all facilities or parts thereof (or the current amount required if certification is used).

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 for the total of all facilities or parts thereof (or the current amount required if certification is used).

3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P), or Aaa, Aa, or A as issued by Moody's.

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, 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 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 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 Poor's or Moody's, 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 Poor's and Moody's, 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 with 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 section 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 Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

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 Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

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 Poor's or Moody's, 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 33-10-04.1

33-10-04.1-02. Scope. This chapter applies to persons licensed or registered by the department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, ~~to any medical administration or therapy the individual has received, to exposure from individuals administered radioactive material and released in accordance with subsection 12 of section 33-10-07-05, or~~ to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under section 33-10-07.1-32 or to exposure from voluntary participation in medical research programs.

History: Effective March 1, 1994; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-03. Definitions. As used in this chapter:

1. "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

2. "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. Annual limit on intake is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of five-hundredths sievert [5 rem] or a committed dose equivalent of five-tenths sievert [50 rem] to any individual organ or tissue. Annual limit on intake values for intake by ingestion and by inhalation of selected radionuclides are given in table I, columns 1 and 2, of appendix B.

3. "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the assigned protection factor.

4. "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

~~2.~~ 5. "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for class D, days, of less than ten days, for class W, weeks, from ten to

one hundred days, and for class Y, years, of greater than one hundred days. "Lung class" and "inhalation class" are equivalent terms.

~~3.~~ 6. "Declared pregnant woman" means a woman who has voluntarily informed ~~her employer~~ the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

7. "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

~~4.~~ 8. "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of two thousand hours under conditions of light work, results in an intake of one annual limit on intake. The condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for two thousand hours in a year. Derived air concentration values are given in table I, column 3, of appendix B.

~~5.~~ 9. "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take two thousand derived air concentration-hours to represent one annual limit on intake, equivalent to a committed effective dose equivalent of five-hundredths sievert [5 rem].

10. "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

~~6.~~ 11. "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

12. "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

13. "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

14. "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

15. "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

16. "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

~~7.~~ 17. "Inhalation class" [see "class"].

18. "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

~~8.~~ 19. "Lung class" [see "class"].

20. "Negative pressure respirator (tight-fitting)" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

~~9.~~ 21. "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. "Deterministic effect" is an equivalent term.

~~10.~~ 22. "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

23. "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

24. "Powered air-purifying respirator (PAPR)" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

25. "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

26. "Qualitative fit test (QLFT)" means a pass or fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

27. "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.

28. "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

~~11.~~ 29. "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately thirteen consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

~~12.~~ 30. "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the international commission on radiological protection report, ICRP Publication 23, "Report of the Task Group on Reference Man".

~~13.~~ 31. "Respiratory protection equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

~~14.~~ 32. "Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

33. "Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

~~15.~~ 34. "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. "Probabilistic effect" is an equivalent term.

35. "Supplied-air respirator (SAR) or airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

36. "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

37. "User seal check (fit check)" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

~~16.~~ 38. "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five gray [500 rad] in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. ~~(~~At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.~~)~~

~~17.~~ 39. "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole body	1.00[b]

[a] 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

History: Effective March 1, 1994; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04, 28-32-02
Law Implemented: NDCC 23-20.1-03

33-10-04.1-04. Implementation. This chapter ~~shall go into effect on~~ became effective March 1, 1994, and all licensees and registrants must comply by that date except for the following:

1. Any existing license or registration condition that is in place prior to implementation of this chapter and is more restrictive than this chapter

remains in force until there is an amendment or renewal of the license or registration.

2. If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before March 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

3. If a license or registration condition cites provisions of this chapter in effect prior to March 1, 1994, which do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

History: Effective March 1, 1994; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-05. Radiation protection programs.

1. Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See subsection 2 of section 33-10-04.1-15 for recordkeeping requirements relating to these programs.

2. To the extent ~~practicable~~ practical, the licensee or registrant shall use procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

3. At intervals not to exceed twelve months, the licensee or registrant shall review the radiation protection program content and implementation.

4. To implement the as low as is reasonably achievable (ALARA) requirements of subsection 2, and notwithstanding the requirements of subsection 1 of section 33-10-04.1-07, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of one-tenth millisieverts [10 ~~mrem~~ millirems] per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in subsection 3 of section 33-10-04.1-16 and promptly take appropriate corrective action to ensure against recurrence.

History: Effective March 1, 1994; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-06. Occupational dose limits.

1. **Occupational dose limits for adults.**

   a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to subsection 6, to the following dose limits:

      (1) An annual limit, which is the more limiting of:

         (a) The total effective dose equivalent being equal to five-hundredths sievert [5 rem]; or

         (b) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to five-tenths sievert [50 rem].

      (2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

         (a) ~~An eye~~ A lens dose equivalent of fifteen-hundredths sievert [15 rem]; and

         (b) A shallow dose equivalent of five-tenths sievert [50 rem] to the skin of the whole body or to the skin of any extremity.

   b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See paragraphs 1 and 2 of subdivision e of subsection 6.

   c. The assigned deep dose equivalent ~~and shallow dose equivalent shall~~ must be for the ~~portion~~ part of the body receiving the highest exposure ~~determined as follows:~~. The assigned shallow dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure.

      (1) The deep dose equivalent, ~~eye~~ lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(2) ~~Reserved.~~ When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in paragraph 5 of subdivision a of subsection 2 of section 33-10-04.1-09, the effective dose equivalent for external radiation shall be determined as follows:

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

(b) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds twenty-five percent of the limit specified in subdivision a of subsection 1 of section 33-10-04.1-06, the reported deep dose equivalent value multiplied by three-tenths shall be the effective dose equivalent for external radiation.

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

(d) Subparagraphs b and c only apply when all of the following conditions are met:

[1] The individual monitoring devices have not been exposed to radiation from radioactive material.

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

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

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

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

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

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

d. Derived air concentration and annual limit on intake values are presented in table I of appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See subsection 7 of section 33-10-04.1-15.

e. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3 of appendix B.

f. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See subdivision e of subsection 5.

2. **Compliance with requirements for summation of external and internal doses.**

a. If the licensee or registrant is required to monitor pursuant to both subdivision a and subdivision b of subsection 2 of section 33-10-04.1-09, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subdivision a of subsection 2 of section 33-10-04.1-09 or only pursuant to subdivision b of subsection 2 of section 33-10-04.1-09, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subdivision b, subdivision c, and subdivision d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

b. Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation annual limit on intake for each radionuclide~~, or~~;

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by two thousand~~,~~; or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, H_T,50, per unit intake is greater than ten percent of the maximum weighted value of H_T,50, that is, $w_T H_T$,50, per unit intake for any organ or tissue.

c. Intake by oral ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral annual limit on intake, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

d. Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of derived air concentration for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subdivision.

3. **Determination of external dose from airborne radioactive material.**

a. Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, ~~eye~~ lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See appendix B, footnotes 1 and 2.

b. Airborne radioactivity measurements and derived air concentration values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne

radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

4. **Determination of internal exposure.**

   a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to subsection 2 of section 33-10-04.1-09, take suitable and timely measurements of:

      (1) Concentrations of radioactive materials in air in work areas;

      (2) Quantities of radionuclides in the body;

      (3) Quantities of radionuclides excreted from the body; or

      (4) Combinations of these measurements.

   b. Unless respiratory protection equipment is used, as provided in subsection 3 of section 33-10-04.1-11, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

   c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

      (1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record;

      (2) Upon prior approval of the department, adjust the derived air concentration or annual limit on intake values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

      (3) Separately assess the contribution of fractional intakes of class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See appendix B.

   d. If the licensee or registrant chooses to assess intakes of class Y material using the measurements given in paragraph 2 or 3 of subdivision a, the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by subsection 2 or 3 of section

33-10-04.1-16. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the derived air concentration applicable to the mixture for use in calculating derived air concentration-hours shall be either:

(1) The sum of the ratios of the concentration to the appropriate derived air concentration value, that is, D, W, or Y, from appendix B for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive derived air concentration value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the derived air concentration for the mixture shall be the most restrictive derived air concentration of any radionuclide in the mixture.

g. When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

(1) The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in subsection 1 and in complying with the monitoring requirements in subdivision b of subsection 2 of section 33-10-04.1-09~~, and~~;

(2) The concentration of any radionuclide disregarded is less than ten percent of its derived air concentration~~.~~; and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed thirty percent.

h. When determining the committed effective dose equivalent, the following information may be considered:

(1) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one annual limit on intake, or an exposure of two thousand derived air concentration-hours, results in a committed effective dose equivalent of five-hundredths sievert [5 rem] for radionuclides that have their annual limit on intakes or derived air concentrations based on the committed effective dose equivalent.

(2) For an annual limit on intake and the associated derived air concentration determined by the nonstochastic organ dose limit of five-tenths sievert [50 rem], the intake of radionuclides that would result in a committed effective dose equivalent of five-hundredths sievert [5 rem], that is, the stochastic annual limit on intake, is listed in parentheses in table I of appendix B. As a simplifying assumption, the licensee or registrant may use the stochastic annual limit on intake to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic annual limit on intake, the licensee or registrant shall also demonstrate that the limit in subparagraph 2 of paragraph 1 of subdivision a of subsection 1 is met.

5. **Determination of prior occupational dose.**

a. For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to subsection 2 of section 33-10-04.1-09, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of cumulative occupational radiation dose.

b. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures;

(2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(3) All lifetime cumulative occupational radiation dose.

c. In complying with the requirements of subdivision a, a licensee or registrant may:

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year;

(2) Accept, as the record of cumulative radiation dose, an up-to-date department's occupational radiation exposure history form (SFN 19443) or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

(3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

d. (1) The licensee or registrant shall record the exposure history, as required by subdivision a, on the department's occupational radiation exposure history form (SFN 19443), or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the department's occupational radiation exposure history form (SFN 19443) or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the department's occupational radiation exposure history form (SFN 19443) or equivalent indicating the periods of time for which data are not available.

(2) Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in chapter 33-10-04 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on the department's occupational radiation exposure history form (SFN 19443) or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

e. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(1) In establishing administrative controls pursuant to subdivision f of subsection 1 for the current year, that the allowable dose limit for the individual is reduced by twelve and five-tenths millisieverts [1.25 rem] for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

f. The licensee or registrant shall retain the records on the department's occupational radiation exposure history form (SFN 19443) or equivalent until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the department's occupational radiation exposure history form (SFN 19443) or equivalent for three years after the record is made.

6. **Planned special exposures.** A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subsection 1 provided that each of the following conditions is satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the ~~higher~~ dose estimated to result from the planned special exposure are unavailable or impractical.

b. The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

c. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose as low as reasonably achievable considering other risks that may be present.

d. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as

required by subdivision b of subsection 5 during the lifetime of the individual for each individual involved.

e. Subject to subdivision b of subsection 1, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(1) The numerical values of any of the dose limits in subdivision a of subsection 1 in any year; and

(2) Five times the annual dose limits in subdivision a of subsection 1 during the individual's lifetime.

f. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with subsection 6 of section 33-10-04.1-15 and submits a written report in accordance with subsection 4 of section 33-10-04.1-16.

g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within thirty days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to subdivision a of subsection 1 but shall be included in evaluations required by subdivisions d and e.

7. **Occupational dose limits for minors.** The annual occupational dose limits for minors are ten percent of the annual occupational dose limits specified for adult workers in subsection 1.

8. **Dose equivalent to ~~an~~ the embryo or fetus.**

a. The licensee or registrant shall ensure that the dose equivalent to ~~an~~ the embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five millisievert [0.5 rem]. See subsection 7 of section 33-10-04.1-15 for recordkeeping requirements.

b. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in subdivision a (the national council on radiation protection and measurements recommended in NCRP report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than five-tenths millisievert [0.05 rem] to the embryo or fetus be received in any one month).

c. The dose equivalent to ~~an~~ the embryo or fetus shall be taken as the sum of:

(1) The deep dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.

d. If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo or fetus has exceeded four and five-tenths millisievert [0.45 rem], the licensee or registrant shall be deemed to be in compliance with subdivision a of subsection 8 of section 33-10-04.1-06 if the additional dose equivalent to the embryo or fetus does not exceed five-tenths millisievert [0.05 rem] during the remainder of the pregnancy.

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

33-10-04.1-07. Radiation dose limits for individual members of the public.

1. **Dose limits for individual members of the public.**

a. Each licensee or registrant shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one millisievert [0.1 rem] in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with ~~subsection 12 of~~ section ~~33-10-07-05~~ 33-10-07.1-32, voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with subsection 3 of section 33-10-04.1-14. Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994, and met the previous requirements of five millisievert [0.5 rem] in a year; and

(2) The dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in

accordance with subsection 12 of section 33-10-07-05 does not exceed two-hundredths millisievert [0.002 rem] in any one hour.

b. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

c. Notwithstanding paragraph 1 of subdivision a of subsection 1 of this section, a licensee may permit visitors to an individual who cannot be released, under section 33-10-07.1-32, to receive a radiation dose greater than one millisievert [100 millirems] if:

(1) The radiation dose received does not exceed five millisieverts [500 millirems]; and

(2) The authorized user, as defined in chapter 33-10-07.1, has determined before the visit that it is appropriate.

d. A licensee, registrant, or an applicant for a license or registration may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of five ~~millisievert~~ millisieverts [0.5 rem]. This application shall include the following information:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in subdivision a;

(2) The licensee's or registrant's program to assess and control dose within the five ~~millisievert~~ millisieverts [0.5 rem] annual limit; and

(3) The procedures to be followed to maintain the dose as low as reasonably achievable.

~~d.~~ e. In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of the United States environmental protection agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

~~e.~~ f. The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

2. **Compliance with dose limits for individual members of the public.**

a. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in subsection 1.

b. A licensee or registrant shall show compliance with the annual dose limit in subsection 1 by:

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(2) Demonstrating that:

(a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table II of appendix B; and

(b) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed two-hundredths millisievert [0.002 rem] in an hour and five-tenths millisievert [0.05 rem] in a year.

c. Upon approval from the department, the licensee or registrant may adjust the effluent concentration values in appendix B, table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

History: Effective March 1, 1994; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-08. Testing for leakage or contamination of sealed sources.

~~1. Testing for leakage or contamination of sealed sources.~~

~~a.~~ 1. The licensee or registrant in possession of any sealed source shall assure that:

~~(1)~~ a. Each sealed source, except as specified in subdivision b of subsection 1, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor

indicating that the sealed source was tested within six months before transfer to the licensee or registrant.

~~(2)~~ b. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the department, after evaluation of information specified by paragraphs 4 and 5 of subdivision k of subsection 5 of section 33-10-03-05, an agreement state, a licensing state, or the United States nuclear regulatory commission.

~~(3)~~ c. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the department, after evaluation of information specified by paragraphs 4 and 5 of subdivision ~~k~~ j of subsection 5 of section 33-10-03-05, an agreement state, a licensing state, or the United States nuclear regulatory commission.

~~(4)~~ d. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.

~~(5)~~ e. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of one hundred eighty-five becquerels [0.005 µCi] of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

~~(6)~~ f. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of thirty-seven becquerels [0.001 µCi] of radon-222 in a twenty-four-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume, and time.

~~(7)~~ g. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of one hundred eighty-five becquerels [0.005 µCi] of a radium daughter which has a half-life greater than four days.

~~b.~~ 2. A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

~~(1)~~ a. Sealed sources containing only radioactive material with a half-life of less than thirty days;

~~(2)~~ b. Sealed sources containing only radioactive material as a gas;

~~(3)~~ c. Sealed sources containing three and seven-tenths megabecquerels [100 µCi] or less of beta or photon-emitting material or three hundred seventy kilobecquerels [10 µCi] or less of alpha-emitting material;

~~(4)~~ d. Sealed sources containing only hydrogen-3;

~~(5)~~ e. Seeds of iridium-192 encased in nylon ribbon; and

~~(6)~~ f. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

~~c.~~ 3. Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the department, an agreement state, a licensing state, or the United States nuclear regulatory commission to perform such services.

~~d.~~ 4. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the department. Records of test results for sealed sources shall be made pursuant to subsection 4 of section 33-10-04.1-15.

~~e.~~ 5. The following shall be considered evidence that a sealed source is leaking:

~~(1)~~ a. The presence of one hundred eighty-five becquerels [0.005 µCi] or more of removable contamination on any test sample.

~~(2)~~ b. Leakage of thirty-seven becquerels [0.001 µCi] of radon-222 per twenty-hour hours for brachytherapy sources manufactured to contain radium.

~~(3)~~ c. The presence of removable contamination resulting from the decay of one hundred eighty-five becquerels [0.005 µCi] or more of radium.

~~f.~~ 6. The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leakage sealed source shall be repaired or disposed of in accordance with this section.

~~g.~~ 7. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to subsection 8 of section 33-10-04.1-16.

History: Effective March 1, 1994; amended effective July 1, 1995; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-09. Survey and monitoring.

1. **General.**

   a. Each licensee or registrant shall make, or cause to be made, surveys that:

      (1) Are necessary for the licensee or registrant to comply with this chapter; and

      (2) Are ~~necessary~~ reasonable under the circumstances to evaluate:

         (a) ~~Radiation~~ The magnitude and extent of radiation levels;

         (b) Concentrations or quantities of radioactive material; and

         (c) The potential radiological hazards that could be present.

   b. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed twelve months for the radiation measured except when a more frequent interval is specified in another applicable section of these rules or a license condition.

   c. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with subsection 1 of section 33-10-04.1-06, with other provisions of this article, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) Holding current personnel dosimetry accreditation from the national voluntary laboratory accreditation program (NVLAP) of the national institute of standards and technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

d. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

2. **Conditions requiring individual monitoring of external and internal occupational dose.** Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. At a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

(1) Adults likely to receive, in one year from sources external to the body, a dose in excess of ten percent of the limits in subdivision a of subsection 1 of section 33-10-04.1-06;

(2) Minors ~~and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of ten percent of any of the applicable limits in subsections 7 or 8 of section 33-10-04.1-06; and~~ likely to receive, in one year from radiation sources external to the body, a deep dose equivalent in excess of one millisievert [100 millirems], a lens dose equivalent in excess of one and five-tenths millisieverts [150 millirems], or a shallow dose equivalent to the skin of the whole body or to the skin of any extremity in excess of five millisieverts [500 millirems] (the assigned shallow dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body a deep dose equivalent in excess of one millisievert [100 millirems];

(4) Individuals entering a high or very high radiation area; and

~~(4)~~ (5) ~~Reserved.~~ Individuals working with medical fluoroscopic equipment.

(a) An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman, pursuant to subdivision a of subsection 8 of section 33-10-04.1-06, shall be located under the protective apron at the waist.

(b) An individual monitoring device used for lens dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron.

(c) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to paragraph 2 of subdivision c of subsection 1 of section 33-10-04.1-06, it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

b. Each licensee or registrant shall monitor, to determine compliance with subsection 4 of section 33-10-04.1-06, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable annual limit on intake in table I, columns 1 and 2, of appendix B; ~~and~~

(2) Minors ~~and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of five-tenths millisievert [0.05 rem].~~ likely to receive, in one year, a committed effective dose equivalent in excess of one-tenth millisievert [10 millirems]; and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of one millisievert [100 millirems].

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

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

b. An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman, pursuant to subdivision a of subsection 8 of section 33-10-04.1-06, shall be located at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subparagraph a of paragraph 2 of subdivision a of subsection 1 of section 33-10-04.1-06, shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye; and

d. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subparagraph b of paragraph 2 of subdivision a of subsection 1 of section 33-10-04.1-06, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

History: Effective March 1, 1994; amended effective July 1, 1995; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-11. Respiratory protection and controls to restrict internal exposure in restricted areas.

1. **Use of process or other engineering controls.** The licensee or registrant shall use, to the extent practical, process or other engineering controls, such as, containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

2. **Use of other controls.**

   a. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant, consistent with maintaining the total effective dose equivalent as low as is reasonably achievable (ALARA), shall increase monitoring and limit intakes by one or more of the following means:

~~a.~~ (1) Control of access;

~~b.~~ (2) Limitation of exposure times;

~~c.~~ (3) Use of respiratory protection equipment; or

~~d.~~ (4) Other controls.

b. If the licensee performs an as low as reasonably achievable (ALARA) analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

3. **Use of individual respiratory protection equipment.**

a. If the licensee or registrant ~~uses~~ assigns or permits the use of respiratory protection equipment to limit ~~intakes~~ intake of radioactive material pursuant to subsection 2:

(1) Except as otherwise provided in ~~paragraph 2~~ this section, the licensee or registrant shall use only respiratory protection equipment that is tested and certified ~~or had certification extended~~ by the national institute for occupational safety and health ~~and the mine safety and health administration~~ (NIOSH).

(2) The licensee or registrant may use respiratory protection equipment that has not been tested or certified by the national institute for occupational safety and health ~~and the mine safety and health administration, has not had certification extended by the national institute for occupational safety and health and the mine safety and health administration~~, or for which there is no schedule for testing or certification, provided the licensee or registrant has submitted to the department and the department has approved an application for authorized use of that respiratory protection equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the respiratory protection equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(3) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(a) Air sampling sufficient to identify the potential hazard, permit proper respiratory protection equipment selection, and estimate ~~exposures~~ doses;

(b) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(c) Testing of respiratory protection equipment for operability, including user seal check for face sealing devices and functional check for others, immediately prior to each use;

(d) Written procedures regarding ~~selection, fitting, issuance, maintenance, and testing of respiratory protection equipment, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and~~:

[1] Monitoring, including air sampling and bioassays;

[2] Supervision and training of respirator users;

[3] Fit testing;

[4] Respirator selection;

[5] Breathing air quality;

[6] Inventory and control;

[7] Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

[8] Recordkeeping;

[9] Limitations on periods of respirator use and relief from respirator use;

[10] The use of process or other engineering controls, instead of respiratory protection equipment; and

[11] The routine, nonroutine, and emergency use of respiratory protection equipment;

(e) Determination by a physician ~~prior to initial fitting of respiratory protection equipment, and either every twelve months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.~~ that the individual user is medically fit to use respiratory protection equipment, before:

[1] The initial fitting of a face sealing respirator;

[2] Before the first field use of nonface sealing respirators; and

[3] Either every twelve months thereafter, or periodically at a frequency determined by a physician; and

(f) Fit testing, with fit factor greater than or equal to ten times the assigned protection factor for negative pressure devices, and a fit factor greater than or equal to five hundred for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight-fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(4) ~~The licensee or registrant shall issue a written policy statement on respiratory protection equipment usage covering:~~

~~(a) The use of process or other engineering controls, instead of respiratory protection equipment;~~

~~(b) The routine, nonroutine, and emergency use of respiratory protection equipment; and~~

~~(c) The length of periods of respiratory protection equipment use and relief from respiratory protection equipment use.~~

~~(5)~~ The licensee or registrant shall advise each respiratory protection equipment user that the user may leave the area at any time for relief from respiratory protection equipment use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

~~(6)~~ (5) The licensee or registrant shall use respirator protection equipment within the equipment manufacturer's expressed limitations for type and mode of use ~~and~~. The licensee or registrant shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee or registrant shall provide ~~proper visual~~ for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or

radiological protection equipment. The licensee or registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator and shall consider other special capabilities, such as adequate skin protection, when needed.

(6) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(7) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the compressed gas association in publication G-7.1, "Commodity Specification for Air" 1997 and included in the regulations of the United States occupational safety and health administration [29 CFR 1910.134(i)(1)(ii)(A) through (E)]. Grade D quality air criteria, including:

(a) Oxygen content (v/v) of 19.5 through 23.5 percent;

(b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;

(c) Carbon monoxide (CO) content of ten parts per milion or less;

(d) Carbon dioxide content of one thousand parts per million or less; and

(e) Lack of noticeable odor.

(8) The licensee shall ensure that no objects, materials, or substances, such as facial hair, or any conditions that interfere with the face to facepiece seal or valve function, and that are under the control of the respirator wearer, are

present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

b. When estimating ~~exposure of~~ dose to individuals ~~to~~ from intake of airborne radioactive materials, ~~the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to subsection 2, provided that the following conditions, in addition to those in subdivision a, are satisfied:~~

~~(1) The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in appendix B, table I, column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in subsection 2 of keeping the total effective dose equivalent as low as is reasonably achievable, the licensee or registrant may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent as low as is reasonably achievable. The~~ the concentration of radioactive material in the air that is inhaled when ~~respiratory protection equipment is~~ respirators are worn ~~may be~~ is initially ~~estimated by dividing the average concentration in air, during each period of uninterrupted use, by the~~ assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the ~~exposure~~ dose is later found to be greater than initially estimated, the corrected value shall be used; however, if the exposure is later found to be less than initially estimated, the corrected value may be used.

~~(2) The licensee or registrant shall obtain authorization from the department before assigning respiratory protection factors in excess of those specified in appendix A. The department may authorize a licensee or registrant to use higher protection factors on receipt of an application that:~~

~~(a) Describes the situation for which a need exists for higher protection factors; and~~

~~(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.~~

~~c. In an emergency, the licensee or registrant shall use as emergency equipment only respiratory protection equipment that has been~~

~~specifically certified or had certification extended for emergency use by the national institute for occupational safety and health and the mine safety and health administration.~~

~~d. The licensee or registrant shall notify the department in writing at least thirty days before the date that respiratory protection equipment is first used pursuant to either subdivision a or b.~~

4. **Further restrictions on the use of respiratory protection equipment.** The department may impose restrictions in addition to those in subsection 2, subsection 3, and appendix A to:

   a. Ensure that the respiratory protection program of the licensee or registrant is adequate to limit ~~exposures of~~ doses to individuals ~~to~~ from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent as low as reasonably achievable; and

   b. Limit the extent to which a licensee or registrant may use respiratory protection equipment instead of process controls or other engineering controls.

5. **Application for use of higher assigned protection factors.** The licensee or registrant shall obtain authorization from the department before using assigned protection factors in excess of those specified in appendix A. The department may authorize a licensee or registrant to use higher assigned protection factors on receipt of an application that:

   a. Describes the situation for which a need exists for higher protection factors; and

   b. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

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

33-10-04.1-12. ~~Storage~~ Security and control of licensed or registered sources of radiation.

1. ~~**Security of stored sources of radiation.**~~ The licensee or registrant shall secure radioactive material from unauthorized removal or access ~~licensed or registered sources of radiation that are stored in unrestricted areas~~.

2. ~~**Control of sources of radiation not in storage.**~~

~~a. The licensee or registrant shall control and maintain constant surveillance of licensed or registered radioactive material that is in an unrestricted area and that is not in storage or in a patient who has been released in accordance with the patient release criteria in subsection 12 of section 33-10-07-05.~~

~~b. The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.~~ The licensee or registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of radioactive material that is in an unrestricted area and that is not in storage.

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

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

History: Effective March 1, 1994; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-04.1-13. Precautionary procedures.

1. **Caution signs.**

   a. Standard radiation symbol. Unless otherwise authorized by the department, the symbol prescribed by this subsection shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as shown in appendix H.

   b. Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of subdivision a, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

   c. Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

2. **Posting requirements.**

a. Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION~~,~~: RADIATION AREA".

b. Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION~~,~~: HIGH RADIATION AREA" or "DANGER~~,~~: HIGH RADIATION AREA".

c. Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER~~,~~: VERY HIGH RADIATION AREA".

d. Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION~~,~~: AIRBORNE RADIOACTIVITY AREA" or "DANGER~~,~~: AIRBORNE RADIOACTIVITY AREA".

e. Posting of areas or rooms in which licensed or registered material is used or stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten times the quantity of such material specified in appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION~~,~~: RADIOACTIVE ~~MATERIAL(S)~~ MATERIAL" or "DANGER~~,~~: RADIOACTIVE ~~MATERIAL(S)~~ MATERIAL".

3. **Exceptions to posting requirements.**

a. A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

(2) The area or room is subject to the licensee's or registrant's control.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to subsection 2 provided that the patient could be released from control pursuant to subsection 12 of section 33-10-07-05.

c. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at thirty centimeters from the surface of the sealed source container or housing does not exceed five hundredths millisievert [0.005 rem] per hour.

d. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

4. **Labeling containers and radiation machines.**

a. The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION;: RADIOACTIVE MATERIAL" or "DANGER;: RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

b. Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

c. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

5. **Exemptions to labeling requirements.** A licensee or registrant is not required to label:

a. Containers holding licensed or registered material in quantities less than the quantities listed in appendix C;

b. Containers holding licensed or registered material in concentrations less than those specified in table III of appendix B;

c. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter;

d. Containers when they are in transport and packaged and labeled in accordance with the rules of the United States department of transportation (Labeling of packages containing radioactive

materials is required by the United States department of transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by United States department of transportation rules 49 CFR 173.403(m) and (w) and 173.421-424.);

e. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

f. Installed manufacturing or process equipment, such as piping and tanks.

6. **Procedures for receiving and opening packages.**

a. Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a type A quantity, as defined in section 33-10-13-02 and appendix A of chapter 33-10-13, shall make arrangements to receive:

(1) The package when the carrier offers it for delivery; or

(2) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

b. Each licensee or registrant shall:

(1) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in section 33-10-01-04. Labeled package means posted with a radioactive white I, yellow II, or yellow III label as specified in United States department of transportation rules 49 CFR 172.403 and 172.436-440;

(2) Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the type A quantity, as defined in section 33-10-13-02 and appendix A of chapter 33-10-13. Labeled package means posted with a radioactive white I, yellow II, or yellow III label as specified in United States department of transportation rules 49 CFR 172.403 and 172.436-440; and

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

c. The licensee or registrant shall perform the monitoring required by subdivision b as soon as practical after receipt of the package, but not later than three hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

d. The licensee or registrant shall immediately notify the final delivery carrier and, ~~by telephone and telegram, mailgram, or facsimile,~~ the department by telephone in accordance with contact information in section 33-10-01-13 when:

(1) Removable radioactive surface contamination exceeds the limits of subsection 8 of section 33-10-13-15; or

(2) External radiation levels exceed the limits of subsections 9 and 10 of section 33-10-13-15.

e. Each licensee or registrant shall:

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

f. Licensees or registrants ~~transferring~~ transporting special form sources in vehicles owned or operated by the licensee or registrant to and from a worksite are exempt from the contamination monitoring requirements of subdivision b, but are not exempt from the monitoring requirement in subdivision b for measuring radiation levels that ensures that the source is still properly lodged in its shield.

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

33-10-04.1-14. Waste disposal.

1. **General requirements.**

   a. A licensee or registrant shall dispose of licensed or registered material only:

      (1) By transfer to an authorized recipient as provided in subsection 6 or in chapter 33-10-03, or to the United States department of energy;

      (2) By decay in storage;

      (3) By release in effluents within the limits in subsection 1 of section 33-10-04.1-07; or

      (4) As authorized pursuant to subsection 2, 3, 4, or 5.

   b. A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

      (1) Treatment prior to disposal;

      (2) Treatment or disposal by incineration;

      (3) Decay in storage;

      (4) Disposal at a land disposal facility licensed pursuant to 10 CFR 61; or

      (5) Storage until transferred to a storage or disposal facility authorized to receive the waste.

2. **Method for obtaining approval of proposed disposal procedures.** A licensee or registrant or applicant for a license or registration may apply to the department for approval of proposed procedures, not otherwise authorized in this article, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

   a. A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal;

   b. An analysis and evaluation of pertinent information on the nature of the environment;

c. The nature and location of other potentially affected facilities; and

d. Analyses and procedures to ensure that doses are maintained as low as is reasonably achievable and within the dose limits in this chapter.

3. **Disposal by release into sanitary sewerage.**

a. A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble, or is readily dispersible biological material, in water;

(2) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in table III of appendix B;

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(a) The licensee or registrant shall determine the fraction of the limit in table III of appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in table III of appendix B; and

(b) The sum of the fractions for each radionuclide required by subparagraph a does not exceed unity; and

(4) The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed one hundred eighty-five gigabecquerels [5 μCi] of hydrogen-3, thirty-seven gigabecquerels [1 μCi] of carbon-14, and 37 gigabecquerels [1 μCi] of all other radioactive materials combined.

b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in subdivision a.

4. **Treatment or disposal by incineration.** A licensee or registrant may treat or dispose of licensed or registered material by incineration only in

the form and concentration specified in subsection 5 or as specifically approved by the department pursuant to subsection 2.

5. **Disposal of specific wastes.**

   a. A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

      (1) One and eighty-five one-hundredths kilobecquerels [0.05 µCi], or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

      (2) One and eighty-five one-hundredths kilobecquerels [0.05 µCi], or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

   b. A licensee or registrant shall not dispose of tissue pursuant to paragraph 2 of subdivision a in a manner that would permit its use either as food for humans or as animal feed.

   c. The licensee or registrant shall maintain records in accordance with subsection 9 of section 33-10-04.1-15.

6. **Transfer for disposal and manifests.**

   a. The requirements of this subsection ~~and appendix D~~ and appendix G are designed to ~~control~~:

      (1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in appendix G, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level ~~radioactive~~ waste land disposal facility~~, establish~~;

      (2) Establish a manifest tracking system ~~supplement,~~; and

      (3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

   b. ~~Beginning March 1, 1998, all affected licensees must use appendix G. Prior to March 1, 1998, a low-level radioactive waste disposal facility operator or its regulatory authority may require the shipper to use appendix D or appendix G. Licensees using appendix D shall comply with paragraph 1 of subdivision b of this subsection. Licensees using appendix G shall comply with paragraph 2 of subdivision b.~~

~~(1) Each shipment of radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in section I of appendix D.~~

~~(2)~~ Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the uniform low-level radioactive waste manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G.

c. Each shipment manifest shall include a certification by the waste generator as specified in section II of ~~appendix D or~~ appendix G~~, as appropriate~~.

d. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of ~~appendix D or~~ appendix G~~, as appropriate~~.

7. **Compliance with environmental and health protection rules.** Nothing in subsection 1, 2, 3, 4, 5, or 6 relieves the licensee or registrant from complying with other applicable federal, state, and local rules governing any other toxic or hazardous properties of materials that may be disposed of in accordance with subsection 1, 2, 3, 4, 5, or 6.

History: Effective March 1, 1994; amended effective July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-04.1

33-10-04.1-15. Records.

1. General provisions.

a. Each licensee or registrant shall use the international system units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

b. Notwithstanding the requirements of subdivision a, when recording information on shipment manifests, as required in paragraph 2 of subdivision b of subsection 6 of section 33-10-04.1-14, information must be recorded in the international system of units or in the international system of units and units as specified in subdivision a.

c. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, ~~eye~~ lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

2. Records of radiation protection programs.

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by paragraph 1 of subdivision a until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by paragraph 2 of subdivision a for three years after the record is made.

3. Records of surveys.

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by subsection 1 of section 33-10-04.1-09 and subdivision b of subsection 6 of section 33-10-04.1-13. The licensee or registrant shall retain these records for three years after the record is made.

b. The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:

(1) Records of the results of surveys to determine the dose from external sources of radiation, and used~~,~~ in the absence of or in combination with individual monitoring data~~,~~ in the assessment of individual dose equivalents;

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to subparagraphs a and b of paragraph 3 of subdivision a of subsection 3 of section 33-10-04.1-11; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to March 1, 1994.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

4. Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources (required by subsection 1 of section 33-10-04.1-08) shall be kept in units of becquerel or microcurie and maintained for inspection by the department for five years after the records are made.

5. Records of prior occupational dose.

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in subsection 5 of section 33-10-04.1-06 on the department's occupational radiation exposure history form (SFN 19443) or equivalent until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the department's occupational radiation exposure history form (SFN 19443) or equivalent for three years after the record is made.

b. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

6. Records of planned special exposures.

a. For each use of the provisions of subsection 6 of section 33-10-04.1-06 for planned special exposures, the licensee or registrant shall maintain records that describe:

(1) The exceptional circumstances requiring the use of a planned special exposure;

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(3) What actions were necessary;

(4) Why the actions were necessary;

(5) What precautions were taken to assure that doses were maintained as low as is reasonably achievable;

(6) What individual and collective doses were expected to result; and

(7) The doses actually received in the planned special exposure.

b. The licensee or registrant shall retain the records until the department terminates each pertinent license or registration requiring these records.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

7. Records of individual monitoring results.

a. Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to subsection 2 of section 33-10-04.1-09, and records of doses received during planned special exposures, accidents, and emergency conditions. ~~Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed.~~ These records shall include, when applicable:

(1) The deep dose equivalent to the whole body, ~~eye~~ lens dose equivalent to the eye, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(2) The estimated intake of radionuclides, see subsection 2 of section 33-10-04.1-06;

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to calculate the committed effective dose equivalent pursuant to ~~subdivision~~

subdivisions a and c of subsection 4 of section 33-10-04.1-06 and when required by subsection 2 of section 33-10-04.1-09;

(5) The total effective dose equivalent when required by subsection 2 of section 33-10-04.1-06; and

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

b. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in subdivision a at intervals not to exceed one year.

c. Recordkeeping format. The licensee or registrant shall maintain the records specified in subdivision a on the department's current occupational radiation exposure form (SFN 8416), in accordance with the instructions for the department's current occupational radiation exposure form (SFN 8416), or in clear and legible records containing all the information required by the department's current occupational radiation exposure form (SFN 8416).

d. The licensee or registrant shall maintain the records of dose equivalent to ~~an~~ the embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

e. The licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

f. Upon termination of the license or registration, the licensee or registrant shall permanently store records on the department's occupational radiation exposure history form (SFN 19443) or equivalent, or shall make provision with the department for transfer to the department.

8. Records of dose to individual members of the public.

a. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See subsection 1 of section 33-10-04.1-07.

b. The licensee or registrant shall retain the records required by subdivision a until the department terminates each pertinent license or registration requiring the record.

9. Records of waste disposal.

a. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to subsection 2, 3, 4, or 5 of section 33-10-04.1-14, chapter 33-10-03, or disposal by burial in soil, including burials authorized before October 1, 1982.

b. The licensee or registrant shall retain the records required by subdivision a until the department terminates each pertinent license or registration requiring the record.

Requirements for disposition of these records, prior to license termination, are located in subsection 14 of section 33-10-03-05 and in sections 33-10-04.1-14 and 33-10-04.1-15 for activities licensed or registered under this article.

10. Records of testing entry control devices for very high radiation areas.

a. Each licensee or registrant shall maintain records of tests made pursuant to paragraph 9 of subdivision b of subsection 3 of section 33-10-04.1-10 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records required by subdivision a for three years after the record is made.

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

12. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than one hundred twenty days, in an unsealed form, shall forward the following records to the department:

a. Records of disposal of licensed material made under subsection 2 of section 33-10-04.1-14 ~~(~~including records of burials made before the effective date of this section~~)~~, and subsections 3, 4, and 5 of section 33-10-04.1-14; and

b. Records required by paragraph 4 of subdivision b of subsection 3 of section 33-10-04.1-15.

13. If licensed activities are transferred or assigned in accordance with subdivision b of subsection 7 of section 33-10-03-05, each licensee authorized to possess radioactive material, with a half-life greater than one hundred twenty days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the licensee is terminated:

    a. Records of disposal of licensed material made under subsection 2 of section 33-10-04.1-14 ~~(~~including burials made before the effective date of this section~~)~~, and subsections 3, 4, and 5 of section 33-10-04.1-14; and

    b. Records required by paragraph 4 of subdivision b of subsection 3 of section 33-10-04.1-15.

14. Prior to license termination, each licensee shall forward the records required by subdivision g of subsection 14 of section 33-10-03-05 to the department.

History: Effective March 1, 1994; amended effective May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-09.1

33-10-04.1-16. Reports.

1. **Reports of stolen, lost, or missing licensed or registered sources of radiation.**

    a. Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

        (1) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than one thousand times the quantity specified in appendix C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; ~~or~~

        (2) Within thirty days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than ten times the quantity specified in appendix C that is still missing~~.~~; and

        (3) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

b. Written reports. Each licensee or registrant required to make a report pursuant to subdivision a, within thirty days after making the telephone report, shall make a written report to the department setting forth the following information:

(1) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(5) Actions that have been taken, or will be taken, to recover the source of radiation; and

(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

c. Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within thirty days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the department pursuant to this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

2. **Notification of incidents.**

a. Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:

(a) A total effective dose equivalent of twenty-five one-hundredths sievert [25 rem] or more;

(b) ~~An eye~~ A lens dose equivalent of seventy-five one-hundredths sievert [75 rem] or more; or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of two and five-tenths gray [250 rad] or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four hours, the individual could have received an intake five times the annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

b. Twenty-four-hour notification. Each licensee or registrant, within twenty-four hours of discovery of the event, shall report to the department each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of twenty-four hours:

(a) A total effective dose equivalent exceeding five-hundredths sievert [5 rem];

(b) ~~An eye~~ A lens dose equivalent exceeding fifteen-hundredths sievert [15 rem]; or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding five-tenths sievert [50 rem]; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four hours, the individual could have received an intake in excess of one annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. The licensee or registrant shall prepare each report filed with the department pursuant to this subsection so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

d. Licensees or registrants shall make the reports required by subdivisions a and b to the department by telephone, ~~telegram, mailgram, or facsimile to the department~~ in accordance with contact information contained in section 33-10-01-13.

e. The provisions of this subsection do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to subsection 4.

3. **Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.**

a. Reportable events. In addition to the notification required by subsection 2, each licensee or registrant shall submit a written report within thirty days after learning of any of the following occurrences:

(1) Incidents for which notification is required by subsection 2; ~~or~~

(2) Doses in excess of any of the following:

(a) The occupational dose limits for adults in subsection 1 of section 33-10-04.1-06;

(b) The occupational dose limits for a minor in subsection 7 of section 33-10-04.1-06;

(c) The limits for an embryo or fetus of a declared pregnant woman in subsection 8 of section 33-10-04.1-06;

(d) The limits for an individual member of the public in subsection 1 of section 33-10-04.1-07; ~~or~~

(e) Any applicable limit in the license or registration; or

(f) The as low as is reasonably achievable (ALARA) constraints for air emissions established under subsection 2 of section 33-10-04.1-05.;

(3) Levels of radiation or concentrations of radioactive material in:

(a) A restricted area in excess of applicable limits in the license or registration; or

(b) An unrestricted area in excess of ten times the applicable limit set forth in this chapter or in the license or registration, whether or not involving exposure of

any individual in excess of the limits in subsection 1 of section 33-10-04.1-07; or

(4) For licensees subject to the provisions of United States environmental protection agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

b. Contents of reports.

(1) Each report required by subdivision a shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) Estimates of each individual's dose;

(b) The levels of radiation and concentrations of radioactive material involved;

(c) The cause of the elevated exposures, dose rates, or concentrations; and

(d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, as low as is reasonably achievable (ALARA) constraints, generally applicable environmental standards, and associated license or registration conditions.

(2) Each report filed pursuant to subdivision a shall include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in subsection 8 of section 33-10-04.1-06, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

c. All licensees or registrants who make reports pursuant to subdivision a shall submit the report in writing to the department.

4. **Reports of planned special exposures.** The licensee or registrant shall submit a written report to the department within thirty days following any planned special exposure conducted in accordance with subsection 6 of section 33-10-04.1-06, informing the department that a planned special exposure was conducted and indicating the date the

planned special exposure occurred and the information required by subsection 6 of section 33-10-04.1-15.

5. **Reporting requirements.**

a. Immediate report. Each licensee shall notify the department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four-hour report. Each licensee shall notify the department within twenty-four hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(a) Requires access to the contaminated area, by workers or the public, to be restricted for more than twenty-four hours by imposing additional radiological controls or by prohibiting entry into the area;

(b) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of this chapter for the material; and

(c) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(a) The equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(b) The equipment is required to be available and operable when it is disabled or fails to function; and

(c) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(a) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of this chapter for the material; and

(b) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by subdivisions a and b by telephone to the department. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(a) The caller's name and callback telephone number;

(b) A description of the event, including date and time;

(c) The exact location of the event;

(d) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(e) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by subdivisions a and b shall submit a written followup report within thirty days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

(a) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(b) The exact location of the event;

(c) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(d) Date and time of the event;

(e) Corrective actions taken or planned and the results of any evaluations or assessments; and

(f) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

6. **Reports of individual monitoring.**

a. This section applies to each person licensed or registered by the department to:

(1) Possess or use sources of radiation for purposes of industrial radiography pursuant to chapters 33-10-03 and 33-10-05;

(2) Receive radioactive waste from other persons for disposal pursuant to chapter 33-10-03; or

(3) Possess or use at any time, for processing or manufacturing for distribution pursuant to chapter 33-10-03 or 33-10-07, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

[a] The department may require as a license condition, or by rule, or order pursuant to section 33-10-01-09, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

b. Each licensee or registrant in a category listed in subdivision a shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by subsection 2 of section 33-10-04.1-09 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use the department's current occupational radiation exposure form (SFN 8416) or equivalent or electronic media containing all the information required by the department's current occupational radiation exposure form (SFN 8416).

c. The licensee or registrant shall file the report required by subdivision b, covering the preceding year, on or before April thirtieth of each year. The licensee or registrant shall submit the report to the department.

7. **Notifications and reports to individuals.**

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in subsection 3 of section 33-10-10-02.

b. When a licensee or registrant is required pursuant to this section to report to the department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also provide the individual a copy of the report submitted to the department. Such reports shall be transmitted at a time not later than the transmittal to the department.

8. **Reports of leaking or contaminated sealed sources.** The licensee or registrant shall file a report within five days with the department if the test for leakage or contamination required pursuant to subsection 1 of section 33-10-04.1-08 indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results, and the corrective action taken.

History: Effective March 1, 1994; amended effective July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-09.1

33-10-04.1-17. Additional requirements - Vacating premises. Each specific licensee or registrant shall, no less than thirty days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of ~~his~~ that person's activities, notify the department in writing of intent to vacate. When deemed necessary by the department, the licensee shall decontaminate the premises in accordance with the following or in such other manner as the department may specify.

1. **Premises.** Each licensee before vacating any premises, or transferring the premises shall permanently decontaminate such premises to meet the criteria for decommissioning in section 33-10-04.1-18. A survey shall be made after such decontamination and the department and the landlord or subsequent tenant or transferee shall be provided with a copy of such survey no less than thirty days before vacating or relinquishing possession or control of premises. No such premises may be vacated, sold, or transferred until the decontamination survey has been verified and accepted by the department.

2. **Equipment.** No machinery, instruments, laboratory equipment, or any other property used in contact with, or close proximity to radioactive material at a licensed premises may be assigned, sold, leased, or transferred to an unlicensed person unless such property has been permanently decontaminated below or equal to the standards specified in appendix F. A survey shall be made after such decontamination and the department and subsequent transferee or owner shall be provided with a copy of such survey. No such equipment may be assigned, sold, leased, or transferred until such documentation survey has been verified and accepted by the department.

History: Effective March 1, 1994; amended effective May 1, 1998.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.1

33-10-04.1-18. Radiological criteria for ~~decommissioning~~ license termination.

1. **General provisions.**

   a. The criteria in this section apply to the ~~decommissioning~~ license termination of licensed facilities.

   b. The criteria in this section do not apply to sites which:

      (1) Have been decommissioned prior to ~~January 1, 1997, and met the~~ August 20, 1997, in accordance with criteria identified in the United States nuclear regulatory commission's site decommissioning management plan action plan ~~to ensure timely cleanup of site decommissioning management plan sites in 57 FR 13389;~~ of April 16, 1992 (57 FR 13389);

      (2) Have previously submitted and received department approval on a license termination plan or decommissioning plan that is compatible with the criteria identified in the United States nuclear regulatory commission's site decommissioning management plan action plan ~~to ensure timely cleanup of site decommissioning management plan sites in 57 FR 13389;~~ of April 16, 1992 (57 FR 13389); or

(3) Submit a sufficient license termination plan or decommissioning plan before ~~January 1, 1999~~ August 20, 1998, and such license termination plan or decommissioning plan is approved by the department before ~~January 1, 2000~~ August 20, 1999, and in accordance with the criteria identified in the United States nuclear regulatory commission's site decommissioning management plan action plan ~~to ensure timely cleanup of site decommissioning management plan sites in 57 FR 13389; April 16, 1992. If an environmental impact statement is required in the submittal, and if, because of the environmental impact statement, the department cannot approve the plan before January 1, 2000, then the department may grant an~~ of April 16, 1992 (57 FR 13389), except that if an environmental impact statement is required in the submittal, there will be a provision for day-to-day extension.

c. After a site has been decommissioned and the license terminated in accordance with the criteria in this section, the department will require additional cleanup only if, based on new information, it determines that the criteria of this section were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

d. When calculating total effective dose equivalent to the average member of the critical group, the licensee shall ~~base estimates on the greatest~~ determine the peak annual total effective dose equivalent dose expected within the first one thousand years after decommissioning. ~~Estimates must be substantiated using actual measurements to the maximum extent practical.~~

2. **Radiological criteria for unrestricted use.** A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent to an average member of the critical group that does not exceed twenty-five hundredths millisievert [25 millirem] per year, including that from ground water sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable. Determination of the levels which are as low as reasonably achievable shall take into account consideration of any detriments, such as ~~loss~~ deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

3. **Criteria for license termination under restricted conditions.** A site will be considered acceptable for license termination under restricted conditions if:

a. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions

of subsection 2 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are as low as reasonably achievable. Determination of the levels which are as low as reasonably achievable shall take into account consideration of any detriments, such as ~~loss from transportation~~ traffic accidents, expected to potentially result from decontamination and waste disposal;

b. The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed twenty-five hundredths millisievert [25 millirem] per year;

c. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(1) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in chapter 33-10-03;

(2) Surety method, insurance, or other guarantee method as described in chapter 33-10-03;

(3) A statement of intent in the case of federal, state, or local government licensees, as described in chapter 33-10-03; or

(4) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity;

d. The licensee has submitted a decommissioning plan or license termination plan to the department indicating the licensee's intent to decommission in accordance with chapter 33-10-03, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice. ~~Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:~~

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(a) Whether provisions for institutional controls proposed by the licensee~~:~~:

~~(a)~~ [1] Will provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed twenty-five hundredths millisievert [25 millirems] total effective dose equivalent per year;

~~(b)~~ [2] Will be enforceable; and

~~(c)~~ [3] Will not impose undue burdens on the local community or other affected parties; and

~~(2)~~ (b) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site; and

~~(3)~~ (2) In seeking advice on the issues identified in ~~this subdivision~~ paragraph 1, the licensee shall provide for:

(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

e. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average

member of the critical group is as low as reasonably achievable and would not exceed either:

(1) One millisievert [100 millirems] per year; or

(2) Five millisieverts [500 millirems] per year provided the licensee:

(a) Demonstrates that further reductions in residual radioactivity necessary to comply with the one millisievert [100 millirems] per year value of paragraph 1 are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(b) Makes provisions for durable institutional controls; and

(c) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of subdivision b and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in subdivision c.

4. **Alternate criteria for license termination.**

a. The department may terminate a license using alternate criteria greater than the dose criterion of subsection 2, subdivision b of subsection 3, or item 1 of subparagraph a of paragraph 1 of subdivision d of subsection 3, if the licensee:

~~a.~~ (1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the total dose from all manmade sources combined, other than medical, would be more than the one millisievert [100 millirem] per year limit of section 33-10-04.1-07 ~~would be unlikely~~, by submitting an analysis of possible sources of exposure;

~~b.~~ (2) Has employed to the extent practical restrictions on site use according to the provisions of subsection 3 in minimizing exposures at the site;

~~c.~~ (3) Reduced doses to as low as is reasonably achievable levels~~. Determination of the levels which are as low as reasonably~~

~~achievable shall take~~ taking into ~~account~~ consideration ~~of~~ any detriments, such as ~~loss from transportation~~ traffic accidents, expected to potentially result from decontamination and waste disposal;

~~d.~~ (4) Has submitted a decommissioning plan or license termination plan to the department indicating the licensee's intent to decommission in accordance with subsection 8 of section 33-10-03-05 and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or the license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

~~(1)~~ (a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

~~(2)~~ (b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

~~(3)~~ (c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues~~; and~~.

~~e.~~ b. The use of alternate criteria to terminate a license requires the approval of the department after addressing any comments provided by the United States environmental protection agency, the United States nuclear regulatory commission, and any public comments submitted pursuant to subsection 5.

5. **Public notification and public participation.** Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to subsection 3 or 4, or whenever the department deems such notice to be in the public interest, the department shall provide opportunity for public comment. Public comment procedures shall include the following:

a. Notice shall be given by publication in a newspaper of general circulation in the area where the license is located or in a state publication designed to give public notice; to persons on a mailing list developed by the department, including those who request in writing to be on the list; and by other means if necessary to

assure adequate notice of the affected public. This shall include publishing a notice in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and soliciting comments from affected parties;

b. Notice shall be made to, and comments solicited from, the United States environmental protection agency and United States nuclear regulatory commission for cases where the licensee proposes to release a site pursuant to subsection 4;

c. Notice shall be made to, and comments solicited from, local and state governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning;

~~b.~~ d. The notice shall identify the affected facility; the name and address of the licensee; the name and address of the department; a brief description of the plan; the name, address, and telephone number of a person from whom interested persons may obtain additional information, including copies of the plan, all relevant supporting materials, and all other materials available to the department that are relevant to the decision; a brief description of the comment procedures required by this subsection; and the time and place of any hearing that may be held, including a statement of procedures to request a hearing, unless a hearing has already been scheduled;

~~c.~~ e. The department shall provide at least thirty days for public comment and shall give notice of any public hearing at least thirty days in advance of the hearing; and

~~d.~~ f. The department shall keep a record of the commenters and also of the issues raised during the public participation process. These ~~record~~ records shall be available to the public.

6. **Minimization of contamination.** Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent ~~practical~~ practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent ~~practical~~ practicable, the generation of radioactive waste.

History: Effective May 1, 1998; amended effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04, 23-20.1-04.1

APPENDIX A
ASSIGNED PROTECTION FACTORS FOR RESPIRATORS[1]

Description	Modes[3]	Assigned Protection Factors: Particulates only	Assigned Protection Factors: Particulates, gases & vapors
(1) AIR-PURIFYING RESPIRATORS[6]			
Filtering facepiece[4] disposable	NP	[4]	
Facepiece, half[7]	NP	10	
Facepiece, full	NP	100	
Facepiece, half	PP	50	
Facepiece, full	PP	1000	
Helmet or hood	PP	1000	
Facepiece, loose-fitting	PP	25	
(2) ATMOSPHERE-SUPPLYING RESPIRATORS[5]			
1. Air-line respirator			
Facepiece, half	CF		50
Facepiece, half	D		10
Facepiece, half	PD		50
Facepiece, full	CF		1000
Facepiece, full	D		100
Facepiece, full	PD		1000
Helmet or hood	CF		1000
Facepiece, loose-fitting	CF		25
Suite	CF		[2]
2. Self-contained breathing apparatus (SCBA)			
Facepiece, full	D		100[9]
Facepiece, full	PD		10,000[8]
Facepiece, full	RD		100[9]
Facepiece, full	RP		10,000[8]
3. COMBINATION RESPIRATORS Any combination of air-purifying and atmosphere-supplying respirators		Assigned protection factor for type and mode of operation as listed above.	

FOOTNOTES

1. These assigned protection factors apply only in a respiratory protection program that meets the requirements of this chapter. They are

applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with United States Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B of Chapter 33-10-04.1 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

2. No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements in section 33-10-04.1-11, with the exception of fit testing, are met.

3. The mode symbols are defined as follows:

   CF = continuous flow

   D = demand

   NP = negative pressure, that is, negative phase during inhalation

   PD = pressure demand, that is, always positive pressure

   PP = powered air-purifying

   RD = demand, recirculating

   RP = positive pressure, recirculating

4. Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in subsection 3 of section 33-10-04.1-11 apply. An assigned protection factor has not been assigned for these devices. However, an assigned protection factor equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

5. The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of three is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is

not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

6. Canisters and cartridges shall not be used beyond service-life limitations. Air purifying respirators with assigned protection factors <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with assigned protection factors >100 must be equipped with particulate filters that are at least 99.97 percent efficient. The licensee may apply to the department for the use of an assigned protection factor greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

7. Under-chin type only. No distinction is made in this appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this chapter are met.

8. This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure, such as skin absorption, must be taken into account in such circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

9. The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

APPENDIX B
ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

Introduction

For each radionuclide, table I indicates the chemical form which is to be used for selecting the appropriate annual limit on intake or derived air concentration value. The annual limit on intakes and derived air concentrations for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of one µm, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times of less than ten days for D, from ten to one hundred days for W, and of greater than one hundred days for Y. The class (D, W, Y) given in the column headed "class" applies only to the inhalation annual limit on intakes and derived air concentrations given in table I columns 2 and 3. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note:

The values in tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or six hundredths, 6E+2 represents 6×10^{2} or six hundred, and 6E+0 represents 6×10^{0} or six.

Table I "Occupational Values"

Note that the columns in table I of this appendix captioned "oral ingestion annual limit on intake," "inhalation annual limit on intake," and "derived air concentration," are applicable to occupational exposure to radioactive material.

The annual limit on intakes in this appendix are the annual intakes of given radionuclide by "reference man" which would result in either (1) a committed effective dose equivalent of five hundredths sieverts (five rem), stochastic annual limit on intake, or (2) a committed dose equivalent of five tenths sieverts (fifty rem) to an organ or tissue, nonstochastic annual limit on intake. The stochastic annual limit on intakes were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of five hundredths sieverts (five rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, W_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of W_T are listed under the definition of weighting factor in section 33-10-04.1-03. The nonstochastic annual limit on intakes were derived to avoid nonstochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of W_T = 0.06 is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the gastro-intestinal tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.

Note that the dose equivalents for an extremity (hands and forearms, feet, and lower legs), skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an annual limit on intake is defined by the stochastic dose limit, this value alone is given. When an annual limit on intake is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the annual limit on intake for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;

St wall = stomach wall;

Blad wall = bladder wall; and

Bone surf = bone surface.

The use of the annual limit on intakes listed first, the more limiting of the stochastic and nonstochastic annual limit on intakes, will ensure that nonstochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the nonstochastic annual limit on intake is limiting, use of that nonstochastic annual limit on intake is considered unduly conservative, the licensee may use the stochastic annual limit on intake to determine the committed effective dose equivalent. However, the licensee shall also ensure that the five tenths sievert (fifty rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic annual limit on intakes (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, Σ (intake (in μCi) of each radionnuclide/ALI_{ns}) < one. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than 1 - (H_d/50), instead of < one.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the derived air concentration and the annual limit on intake is given by:

DAC = ALI(in μCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] μCi/ml.

where 2 x 10^4 ml is the volume of air breathed per minute at work by reference man under working conditions light work.

The derived air concentration values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. Derived air concentrations based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The annual limit on intake and derived air concentration values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of annual limit on intake and derived air concentration do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See subsection 2 of section 33-10-04.1-06. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, class D, class W, or class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for class D, W, and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations"

The columns in table II of this appendix captioned "effluent concentrations," "air" and "water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of subsection 2 of section 33-10-04.1-07. The concentration values given in columns 1 and 2 of table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of five tenths millisievert (0.05 rem).

Consideration of nonstochastic limits has not been included in deriving the air and water effluent concentration limits because nonstochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the nonstochastic limit was governing in deriving the occupational derived air concentration, the stochastic annual limit on intake was used in deriving the corresponding airborne effluent limit in table II. For this reason, the derived air concentration and airborne effluent limits

are not always proportional as was the case in appendix A of the 1992 revision of chapter 33-10-04.1.

The air concentration values listed in table II, column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation annual limit on intake was divided by 2.4×10^9 (ml), relating the inhalation annual limit on intake to the derived air concentration, as explained above, and then divided by a factor of three hundred. The factor of three hundred includes the following components: a factor of fifty to relate the five hundredths sievert (5 rem) annual occupational dose limit to the one millisievert (0.1 rem) limit for members of the public, a factor of three to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of two to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational derived air concentration in table I, column 3 was divided by two hundred nineteen. The factor of two hundred nineteen is composed of a factor of fifty, as described above, and a factor of four and thirty-eight hundredths relating occupational exposure for two thousand hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of two for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion annual limit on intake and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of fifty and two described above and a factor of 7.3×10^5 (ml) which is the annual water intake of reference man.

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation annual limit on intakes and derived air concentrations, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III "Releases to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in subsection 3 of section 33-10-04.1-14. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion annual limit on intake and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by reference man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a reference man during a year, would result in a committed effective does equivalent of five millisieverts (0.5 rem).

LIST OF ELEMENTS

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Mercury	Hg	80
Aluminum	Al	13	Molybedenum	Mo	42
Americium	Am	95	Neodymium	Nd	60
Anitimony	Sb	51	Neptunium	Np	93
Argon	Ar	18	Nickel	Ni	28
Arsenic	As	33	Niobium	Nb	41
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Palladium	Pd	46
Berkelium	Bk	97	Phosphorus	P	15
Beryllium	Be	4	Platinum	Pt	78
Bismuth	Bi	83	Plutonium	Pu	94
Bromine	Br	35	Polonium	Po	84
Cadmium	Cd	48	Potassium	K	19
Calcium	Ca	20	Praseodymium	Pr	59
Californium	Cf	98	Promethium	Pm	61
Carbon	C	6	Protactinium	Pa	91
Cerium	Ce	58	Radium	Ra	88
Cesium	Cs	55	Radon	Rn	86
Chlorine	Cl	17	Rhenium	Re	75
Chromium	Cr	24	Rhodium	Rh	45
Cobalt	Co	27	Rubidium	Rb	37
Copper	Cu	29	Ruthenium	Ru	44
Curium	Cm	96	Samarium	Sm	62
Dysprosium	Dy	66	Scandium	Sc	21
Einsteinium	Es	99	Selenium	Se	34
Erbium	Er	68	Silicon	Si	14
Europium	Eu	63	Silver	Ag	47
Fermium	Fm	100	Sodium	Na	11
Fluorine	F	9	Strontium	Sr	38
Francium	Fr	87	Sulfur	S	16
Gadolinium	Gd	64	Tantalum	Ta	73
Gallium	Ga	31	Technetium	Tc	43

Germanium	Ge	32	Tellurium	Te	52
Gold	Au	79	Terbium	Tb	65
Hafnium	Hf	72	Thalium	Tl	81
Holmium	Ho	67	Thorium	Th	90
Hydrogen	H	1	Thulium	Tm	69
Indium	In	49	Tin	Sn	50
Iodine	I	53	Titanium	Ti	22
Iridium	Ir	77	Tungsten	W	74
Iron	Fe	26	Uranium	U	92
Krypton	Kr	36	Vanadium	V	23
Lanthanum	La	57	Xenon	Xe	54
Lead	Pb	82	Ytterbium	Yb	70
Lutetium	Lu	71	Yttrium	Y	39
Magnesium	Mg	12	Zinc	Zn	30
Manganese	Mn	25	Zirconium	Zr	40
Mendelevium	Md	101			

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APPENDIX D
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APPENDIX E
CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

1. Classification of radioactive waste for land disposal.

a. Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b. Classes of waste.

(1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of class A waste must meet the minimum requirements set forth in subdivision a of subsection 2. If class A waste also meets the stability requirements set forth in subdivision b of subsection 2, it is not necessary to segregate the waste for disposal.

(2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of class B waste must meet both the minimum and stability requirements set forth in subsection 2.

(3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of class C waste must meet both the minimum and stability requirements set forth in subsection 2.

c. Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in table I, classification shall be determined as follows:

(1) If the concentration does not exceed one-tenth times the value in table I, the waste is class A.

(2) If the concentration exceeds one-tenth times the value in table I, but does not exceed the value in table I, the waste is class C.

(3) If the concentration exceeds the value in table I, the waste is not generally acceptable for land disposal.

(4) For wastes containing mixtures of radionuclides listed in table I, the total concentrations shall be determined by the sum of fractions rule described in subdivision g.

TABLE I

Radionuclide	Concentration curie/cubic meter[a]	Concentration nanocurie/gram[b]
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

[a] To convert the curie per cubic meter values to gigabecquerel per cubic meter, multiply the curie per cubic meter value by thirty-seven.

[b] To convert the nanocurie per gram values to becquerel per gram, multiply the nanocurie per gram value by thirty-seven.

d. Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in table I, classification shall be determined based on the concentrations shown in table II. However, as specified in subdivision f, if

radioactive waste does not contain any nuclides listed in either table I or II, it is a class A.

(1) If the concentration does not exceed the value in column 1, the waste is class A.

(2) If the concentration exceeds the value in column 1 but does not exceed the value in column 2, the waste is class B.

(3) If the concentration exceeds the value in column 2 but does not exceed the value in column 3, the waste is class C.

(4) If the concentration exceeds the value in column 3, the waste is not generally acceptable for near-surface disposal.

(5) For wastes containing mixtures of the radionuclides listed in table II, the total concentration shall be determined by the sum of fractions rule described in subdivision g.

TABLE II

Radionuclide	Concentration, curie per cubic meter*		
	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

* To convert the curie per cubic meter value to gigabecquerel per cubic meter, multiply the curie per cubic meter value by thirty-seven. There are no limits established for these radionuclides in class B or class C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be class B unless the concentrations of other radionuclides in table II determine the waste to be class C independent of these radionuclides.

e. Classification determined by both long-lived and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in table I and some of

which are listed in table II, classification shall be determined as follows:

(1) If the concentration of a radionuclide listed in table I is less than one-tenth times the value listed in table I, the class shall be that determined by the concentration of radionuclides listed in table II.

(2) If the concentration of a radionuclide listed in table I exceeds one-tenth times the value listed in table I, but does not exceed the value in table I the waste shall be class C, provided the concentration of radionuclides listed in table II does not exceed the value shown in column 3 of table II.

f. Classification of wastes with radionuclides other than those listed in tables I and II. If the waste does not contain any radionuclides listed in either table I or II, it is class A.

g. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than one if the waste class is to be determined by that column. Example: A waste contains strontium-90 in a concentration of one and eighty-five-hundredths terabecquerels per cubic meter (50 Ci/M^3) and cesium-137 in a concentration of eight hundred fourteen gigabecquerels per cubic meter (22Ci/m^3). Since the concentrations both exceed the values in column 1, table II, they must be compared to column 2 values. For strontium-90 fraction, fifty divided by one hundred fifty is one-third, for cesium-137 fraction, twenty-two divided by forty-four is one-half; the sum of the fractions is eighty-three hundredths. Since the sum is less than one, the waste is class B.

h. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

2. Radioactive waste characteristics.

a. The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of chapter 33-10-04.1, the site license conditions shall govern.

(2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(4) Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume.

(5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with paragraph 8.

(7) Waste must not be pyrophoric material. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable. (See section 33-10-01-04 for the definition of pyrophoric.)

(8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed one and on-half atmospheres at twenty degrees Celsius. Total activity shall not exceed three and seven-tenths terabecquerels (100 Ci) per container.

(9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated or reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

b. The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not

degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(2) Notwithstanding the provisions in paragraphs 3 and 4 of subdivision a of subsection 2, liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.

(3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

3. Labeling. Each package of waste shall be clearly labeled to identify whether it is class A, class B, or class C waste, in accordance with subsection 1.

APPENDIX F
Standards for Unrestricted Areas

(a) Surface contamination limits

(1) Alpha emitters

(i)	Removable:	0.555 Bq/100 cm²	15 pCi/100 cm²	= 33 dpm/100 cm²	average over any one surface
		1.665 Bq/100 cm²	45 pCi/100 cm²	= 100 dpm/100 cm²	maximum
(ii)	Total (fixed):	166.5 Bq/100 cm²	450 pCi/100 cm²	= 1000 dpm/100 cm²	average over any one surface
		832.5 Bq/100 cm²	2250 pCi/100 cm²	= 5000 dpm/100 cm²	maximum or
		2.5 µSv/hr	(0.25 mrem)/hr	maximum at 1 cm from surface	

(2) Beta-Gamma emitters

(i)	Removable: (all beta-gamma emitters except hydrogen-3)	3.7 Bq/100 cm²	100 pCi/100 cm²	average over any one surface
		18.5 Bq/100 cm²	500 pCi/100 cm²	maximum
	Removable: (hydrogen-3)	37 Bq/100 cm²	1000 pCi/100 cm²	average over any one surface
		185 Bq/100 cm²	5000 pCi/100 cm²	maximum
(ii)	Total (fixed):	2.5 µSv/hr	(0.25 mrem)/hr	maximum at 1 cm from surface

(b) Concentration in air and water: Appendix B, table II of chapter 33-10-04.1.

(c) Concentrations in soil and other materials except water:

(1) Radioactive material except source material and radium: Schedule A, column II of chapter 33-10-03.

(2) Source material and radium in soil: Concentration of radionuclides above background concentrations for total radium, averaged over areas of one hundred square meters, shall not exceed:

(i) Five picocuries per gram of dry soil, averaged over the first fifteen centimeters below the surface; and

(ii) Five picocuries per gram of dry soil, averaged over layers of fifteen centimeters thickness more than fifteen centimeters below the surface.

(3) Source material and radium in other materials: Concentration of radionuclides above background concentrations for total radium shall not exceed five picocuries per gram.

(d) The level of gamma radiation measured at a distance of one hundred centimeters from the surface shall not exceed background.

APPENDIX G
REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest.

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest (Federal OMB Control Numbers 3150-0164, -0165, and -0166) reflecting information requested on applicable United States nuclear regulatory commission (NRC) Forms 540 (uniform low-level radioactive waste manifest (shipping paper)) and 541 (uniform low-level radioactive waste manifest (container and waste description)) and, if necessary, on an applicable NRC Form 542 (uniform low-level radioactive waste manifest (manifest index and regional compact tabulation)). Nuclear regulatory commission Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the department to comply with the manifesting requirements of chapter 33-10-04.1 when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this appendix; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste".

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest. Nuclear regulatory commission Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the information and records management branch, office of information resources management, United States nuclear regulatory commission, Washington, D.C. 20555, telephone (301) 415-7232.

This appendix includes information requirements of the department of transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet environmental protection agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not

addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the uniform low-level radioactive waste manifest required by this chapter.

As used in this appendix, the following definitions apply:

"Chelating agent" has the same meaning as that given in chapter 33-10-01.

"Chemical description" means a description of the principal chemical characteristics of low-level radioactive waste.

"Computer-readable medium" means that the regulatory agency's computer can transfer the information from the medium into its memory and process the data.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.

"Decontamination facility" means a facility operating under a commission or agreement state license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this chapter, is not considered to be a consignee for LLW shipments.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"EPA identification number" means the number received by a transporter following application to the administrator of the environmental protection agency as required by 40 CFR part 263.

"Generator" means a licensee operating under a commission or agreement state license who (1) is a waste generator as defined in this chapter, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

"High integrity container (HIC)" means a container commonly designed to meet the structural stability requirements of the United States nuclear regulatory commission in 10 CFR 61.56, and to meet department of transportation requirements for a type A package.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive waste. For purposes of this chapter, a "geologic repository" as defined in 10 CFR part 60 or 63 is not considered a "land disposal facility".

Nuclear regulatory commission Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms referenced in this appendix. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Package" means the assembly of components necessary to ensure compliance with the packaging requirements of United States department of transportation regulations, together with its radioactive contents, as presented for transport.

"Physical description" means the items called for on NRC Form 541 to describe a low-level radioactive waste.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means NRC Form 540 (or equivalent) and, if required, NRC Form 540A (or equivalent) which includes the information required by the department of transportation in 49 CFR part 172.

"Source material" has the same meaning as that given in chapter 33-10-01.

"Special nuclear material" has the same meaning as that given in chapter 33-10-01.

"Uniform low-level radioactive waste manifest" or "uniform manifest" means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Waste collector" means an entity, operating under a commission or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

"Waste generator" means an entity, operating under a commission or agreement state license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste".

"Waste processor" means an entity, operating under a commission or agreement state license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

Information Requirements.

A. General Information.

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information.

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information.

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than one-tenth percent chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 6155. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified.

D. Uncontainerized Waste Information.

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds one-tenth percent by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information.

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this appendix). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in

solidification/stabilization media), the identities and activities of individual radionuclides contained in these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than one-tenth percent chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification.

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the department of transportation and the commission. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

III. Control and Tracking.

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs a through i. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs d through i. A licensee shall:

(a) Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

(b) Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal

container) of waste to identify whether it is class A waste, class B waste, class C waste, or greater than class C waste, in accordance with 10 CFR 61.55;

(c) Conduct a quality assurance program to assure compliance with 10 CFR 61.55 and 10 CFR 61.56 (the program must include management evaluation of audits);

(d) Prepare the NRC uniform low-level radioactive waste manifest as required by this appendix;

(e) Forward a copy or electronically transfer the uniform low-level radioactive waste manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

(f) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph e;

(g) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(h) Retain a copy of or electronically store the uniform low-level radioactive waste manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR Parts 30, 40, and 70; and

(i) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with item E of this portion of the appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

(a) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(b) Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

(c) Forward a copy or electronically transfer the uniform low-level radioactive waste manifest to the intended consignee so that either:

(1) Receipt of the manifest precedes the LLW shipment; or

(2) The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

(d) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph c;

(e) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(f) Retain a copy of or electronically store the uniform low-level radioactive waste manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70;

(g) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with item E of this portion of the appendix; and

(h) Notify the shipper, the department, and the administrator of the nearest commission regional office when any shipment, or part of a shipment, has not arrived within sixty days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

(a) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(b) Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in item E of portion I of this appendix;

(c) Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

(d) Label each package of waste to identify whether it is class A waste, class B waste, or class C waste, in accordance with 10 CFR 61.55 and 10 CFR 61.57;

(e) Conduct a quality assurance program to assure compliance with 10 CFR 61.55 and 10 CFR 61.56 (the program shall include management evaluation of audits);

(f) Forward a copy or electronically transfer the uniform low-level radioactive waste manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

(g) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph f;

(h) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(i) Retain a copy of or electronically store the uniform low-level radioactive waste manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70;

(j) For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with item E of this portion of the appendix; and

(k) Notify the shipper, the department, and the administrator of the nearest commission regional office when any shipment, or part of a shipment, has not arrived within sixty days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

(a) Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the uniform low-level radioactive waste manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

(b) Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(1) until the department or commission terminates the license; and

(c) Notify the shipper, the department, and the administrator of the nearest commission regional office when any shipment, or part of a shipment, has not arrived within sixty days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

(a) Be investigated by the shipper if the shipper has not received notification or receipt within twenty days after transfer; and

(b) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the department and the nearest commission regional office. Each licensee who conducts a trace investigation shall file a written report with the department and the appropriate nuclear regulatory commission regional office within two weeks of completion of the investigation.

CHAPTER 33-10-05

33-10-05-02. Scope. This chapter applies to all licensees or registrants who use sources of radiation for industrial radiography. Except for those requirements of this chapter clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this chapter. This chapter does not apply to medical uses of radioactive material.

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

33-10-05-03. Definitions. As used in this chapter, the following definitions apply:

1. "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

2. "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, e.g., guide tube, control tube, control or drive cable, removable source stop, J tube and collimator when it is used as an exposure head.

3. "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meets the ~~conditions~~ dose limits for individual members of the public as specified in subsection 1 of section 33-10-04.1-07.

~~2.~~ 4. "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet X-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of ionizing radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

~~3.~~ 5. "Certified cabinet X-ray system" means an X-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

6. "Certifying entity" means an independent certifying organization or an agreement state whose industrial radiographer certification program has been reviewed and found to meet the applicable parts of appendix B of this chapter or an independent certifying organization or radiation control agency whose X-ray or combination certification requirements, or both, have been reviewed and found to be equivalent to criteria established by the conference of radiation control program directors.

~~4.~~ 7. "Collimator" means a ~~device used to limit the size, shape, and direction of the primary~~ radiation ~~beam~~ shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

8. "Control or drive cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

9. "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

10. "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

11. "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.

12. "Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

13. "Guide tube projection sheath" means a flexible or rigid tube, i.e., J tube for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

14. "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process including, but not limited to, taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the hours of hands-on experience required for a radiation safety officer or radiographer.

15. "Independent certifying organization" means an independent organization that meets the definition of certifying entity in this section.

~~5.~~ 16. "Industrial radiography" or "radiography" means the examination of the ~~macroscopic~~ structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

17. "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

~~6.~~ 18. "Lixiscope" means a portable light-intensified imaging device using a sealed source.

19. "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

~~7.~~ 20. "Permanent radiographic installation" means ~~a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed~~ an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed and meets all of the requirements of subsection 10 of section 33-10-05-04.

~~8.~~ 21. "Personal supervision" means guidance and instruction provided to a ~~radiographer trainee~~ radiographer's assistant by a qualified radiographer ~~instructor~~ who is physically present at the site, in visual contact with the ~~trainee~~ assistant while the ~~trainee~~ assistant is using sources of radiation and associated equipment, and in such proximity that immediate assistance can be given if required.

22. "Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography, including use of all appropriate equipment and procedures.

23. "Radiation safety officer for industrial radiography" means an individual with the knowledge of and responsibility for the overall radiation safety program, who has the authority to enforce the appropriate radiation protection rules, standards and practices on behalf of the licensee, and who meets the requirements of subsection 2 of section 33-10-05-05.

~~9.~~ 24. "Radiographer" means any individual who has successfully completed the training, testing, and documentation requirements of this chapter, and who performs or who in attendance at the site where the sealed source or sources are being used personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of this article and all license ~~(~~or certificate of registration~~)~~ conditions.

~~10. "Radiographer instructor" means any radiographer who has been authorized by the department to provide on-the-job training to radiographer trainees in accordance with subdivision e of subsection 5 of section 33-10-05-06.~~

~~11. "Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of their instruction.~~

25. "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, sources of radiation or radiation survey instruments in industrial radiography.

26. "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria as specified in this chapter.

~~12.~~ 27. "Radiographic exposure device" also called a camera or a projector means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

28. "Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device or with a radiation machine. Activities include, but are not limited to using, transporting except when being transported by a common or contract carrier, or storing at a temporary jobsite, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

~~13.~~ 29. "Radiographic personnel" means any radiographer~~, radiographer instructor,~~ or ~~radiographer trainee~~ radiographer's assistant.

~~14.~~ 30. "Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

31. "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

32. "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~15.~~ 33. "Shielded position" means the location within the radiographic exposure device or ~~storage container which, by manufacturer's design, is the proper location for storage of the sealed~~ source changer where the sealed source is secured and restricted from movement.

~~16.~~ 34. "Shielded-room radiography" means industrial radiography conducted in a room so shielded that every location on the exterior meets the conditions specified in subsection 1 of section 33-10-04.1-07.

35. "Source assembly" or pig tail means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

~~17.~~ 36. "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those ~~source changers~~ also used for transporting and storage of sealed sources.

~~18.~~ 37. "Storage area" means any location, facility, or vehicle ~~which~~ that is used to store, transport, or secure a radiographic exposure device, a storage container, a radiation machine, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, machine, container, or sealed source.

~~19.~~ 38. "Storage container" means a shielded device in which sealed sources are secured and stored.

~~20.~~ 39. "Temporary jobsite" means ~~any~~ a location where ~~industrial radiography is performed other than the locations listed in a specific license or certificate of registration~~ radiographic operations are conducted and where sources of radiation may be stored other than those locations of use authorized on the license or registration.

~~21.~~ 40. "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the United States department of transportation.

41. "Underwater radiography" means industrial radiography performed when the radiographic exposure device or related equipment are beneath the surface of the water.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-04. Equipment control.

1. **Performance requirements for industrial radiography equipment.** Equipment used in industrial radiographic operations must meet the following minimum criteria:

   a. Each radiographic exposure device, source assembly, or sealed source, and all associated equipment must meet the requirements specified in American national standards institute (ANSI) N432-1980 "radiological safety for the design and construction of apparatus for gamma radiography", (published in NBS handbook 136, issued January 1981). Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the department may find this an acceptable alternative to actual testing of the component pursuant to the standard.

   b. In addition to the requirements specified in subdivision a, the following requirements apply to radiographic exposure devices and associated equipment, source changers, source assemblies, and sealed sources.

      (1) ~~Each~~ The licensee shall ensure that each radiographic exposure device ~~must have~~ has attached to it ~~by the user,~~ a durable, legible, clearly visible label bearing the:

         (a) Chemical symbol and mass number of the radionuclide in the device;

         (b) Activity and the date on which this activity was last measured;

         (c) Model number or product code and serial number of the sealed source;

         (d) Manufacturer of the sealed source; and

         (e) Licensee's name, address, and telephone number.

      (2) Radiographic exposure devices intended for use as type B transport containers must meet the applicable requirements of 10 CFR part 71.

      (3) Modification of ~~any~~ radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly,

controls, or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in subdivisions a and b, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for ~~routine operation~~ radiographic operations or to source changers.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The radiographic exposure device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lockbox, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers ~~which~~ that must be installed ~~during storage and transportation~~ to protect the source assembly from water, mud, sand, or other foreign matter during storage and transportation.

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER RADIOACTIVE". The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must ~~have passed the~~ be able to withstand a crushing ~~tests for the control tube as specified in American national standards institute N432-1980~~ test and a kinking resistance test that closely approximates the crushing and kinking forces likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the radiographic exposure device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in American national standards institute N432-1980.

(9) Source changers must provide a system for ~~assuring~~ ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the ~~drive~~ control cable to or from a source assembly.

d. Notwithstanding subdivision a, equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the endurance test in American national standards institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the control drive mechanism.

2. **Limits on ~~levels of~~ external radiation ~~for~~ levels from radiographic exposure devices ~~and~~, storage containers, and source changers.** The maximum exposure rate limits for radiograph exposure devices, storage containers, and source changers are two millisieverts [200 millirems] per hour at any exterior surface, and one-tenth millisievert [10 millirems] per hour at one meter from any exterior surface with the sealed source in the shielded position.

~~a. Radiographic exposure devices measuring less than ten centimeters [4 inches] from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of one hundred twenty-nine ten millionths coulombs per kilogram [50 milliroentgens] per hour at fifteen centimeters [6 inches] from any exterior surface of the device. Radiographic exposure devices measuring a minimum of ten centimeters [4 inches] from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of five hundred sixteen ten millionths coulombs per kilogram [200 milliroentgens] per hour at any exterior surface, and two hundred fifty hundred millionths coulombs per kilogram [10 milliroentgens] per hour at one meter [39.4 inches] from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.~~

~~b. Subdivision a of this subsection applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers must meet the requirements of subsection 1, and subsection 2 applies only to storage containers and source changers.~~

3. **Locking of ~~sources of radiation~~ radiographic exposure devices, storage containers, and source changers.**

   a. Each ~~source of radiation~~ radiographic exposure device shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked (and if a keyed-lock, with the key removed at all times) at all times except when under the direct surveillance of a radiographer or ~~radiographer trainee~~ radiographer's assistant, or as may be otherwise authorized pursuant to subsection 1 of section 33-10-05-06. Each storage container and source changer likewise shall be provided with a lock and must be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or ~~radiographer trainee~~ radiographer's assistant.

   b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured to a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

   c. The sealed source must be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey must be performed to determine that the sealed source is in the shielded position pursuant to subdivision b of subsection 3 of section 33-10-05-06.

   d. The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct supervision of a radiographer or a radiographer's assistant.

4. **Storage precautions.**

   a. Locked radiographic exposure devices, source changers, storage containers, and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.

   b. Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary jobsites, if the licensee complies with subdivision c and if the

vehicle does not constitute a permanent storage location as described in subdivision d.

c. If a vehicle is to be used for storage of radioactive material, a vehicle survey must be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in subsection 3 of section 33-10-04.1-16 at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than ninety days and any one or more of the following applies to the location:

(1) Telephone service is established by the licensee.

(2) Industrial radiographic services are advertised for or from the location.

(3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

5. **Radiation survey instruments.**

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and chapter 33-10-04.1. Instrumentation required by this subsection must ~~have a range such that five hundred sixteen billionths coulombs per kilogram [2 milliroentgens] per hour through two hundred fifty millionths coulombs per kilogram [1 roentgen] per hour can be measured~~ be capable of measuring a range from two hundredths millisievert [2 millirems] per hour through one hundredth sievert [1 rem] per hour.

b. Each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed ~~three~~ six months and after ~~each~~ instrument servicing, except for battery changes.

(2) Such that accuracy within plus or minus twenty percent can be demonstrated.

(3) At two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logithmic scale instruments; and ~~at appropriate points~~ for digital instruments, at three points between two

hundredths and ten millisieverts [2 and 1000 millirems] per hour.

c. Records of these calibrations must be maintained for ~~two~~ three years after the calibration date for inspection by the department.

d. Each radiation survey instrument must be checked with a radiation source at the beginning of each day of use and at the beginning of each workshift to ensure it is operating properly.

6. **Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.**

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the department, the United States nuclear regulatory commission, or any agreement state.

b. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six-month period prior to the transfer, the sealed source shall not be put into use until tested.

c. The leak test shall be capable of detecting the presence of one hundred eighty-five becquerels [0.005 microcurie] of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to paragraph 5 of subdivision a of subsection 3 of section 33-10-03-05. Records of leak test results shall be kept in units of becquerels [microcuries] and maintained for inspection by the department for ~~two~~ three years after the required leak test is performed.

d. Any test conducted pursuant to subdivisions b and c which reveals the presence of one hundred eighty-five becquerels [0.005 microcurie] or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with this article. Within five days after obtaining results of the test, the licensee shall file a report with the department describing the equipment involved, the test results, and the corrective action taken.

e. ~~Each radiographic exposure device must have permanently attached to it a durable tag which has, as a minimum, the instruction: "Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found".~~ Each exposure device using depleted uranium shielding and an S-tube configuration must be tested for depleted uranium contamination at intervals not to exceed twelve months. The analysis must be capable of detecting the presence of one hundred eighty-five becquerels [0.005 microcurie] of radioactive material on the test sample and must be analyzed by a person specifically authorized by the United States nuclear regulatory commission or another agreement state. Should this testing reveal the presence of one hundred eighty-five becquerels [0.005 microcurie] or more of removable depleted uranium contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. Depleted uranium shielded devices do not have to be tested for depleted uranium contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for depleted uranium contamination if the interval of storage exceeded twelve months. Records of depleted uranium leak tests must be kept in units of becquerels [microcuries] and maintained for inspection by the department for three years after the required test is performed.

7. **Quarterly inventory.** Each licensee shall conduct a ~~quarterly~~ physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices containing depleted uranium received ~~or~~ and possessed by the licensee. The records of the inventories shall be maintained for ~~two~~ three years from the date of the inventory for inspection by the department and shall include the quantities and kinds of radioactive material, the location of sealed sources, the date of the inventory, the name of the individual conducting the inventory, the manufacturer, the model number, and the serial number.

8. **Utilization logs.** Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the department for ~~two~~ three years from the date of the recorded event, showing for each source of radiation the following information:

a. A ~~unique identification, such as~~ description, including make, model, and serial number~~,~~ of each radiation machine, ~~each~~ sealed source, radiographic exposure device, or transport or storage container in which a sealed source is located~~, and each sealed source~~.

b. The ~~identity~~ name and signature of the radiographer to whom assigned.

c. Locations where used and dates of use.

d. The dates each source of radiation is removed from storage and returned to storage.

e. For permanent radiographic installations, the dates each radiation machine is energized.

9. **Inspection and maintenance.**

a. ~~Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day or shift the equipment is used.~~ The radiographer shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

b. ~~Each licensee or registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with the manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the department for two years from the date the inspection and maintenance is performed.~~ Each licensee or registrant shall have written procedures for, and perform:

(1) Inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

(2) Inspection and maintenance necessary to maintain the type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that type B packages are shipped and

maintained in accordance with the certificate of compliance or other approval.

c. If any inspection conducted pursuant to subdivision a or b reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until replaced or repairs have been made.

d. Records of inspection and maintenance shall be maintained for inspection by the department for three years from the date the inspection and maintenance is performed. Each licensee shall maintain records of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments and retain each record for three years after it is made. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair or maintenance, if any, was done.

10. **Permanent radiographic installations.** Permanent radiographic installations having high radiation area entrance controls of the type described in subsection 1 of section 33-10-04.1-10 shall also meet the following requirements:

a. Each entrance that is used for personnel access to the high radiation area shall have ~~both~~ either:

(1) An entrance control of the type described in section 33-10-04.1-10 that reduces the radiation level upon entry into the area; or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed or the machine is energized. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

b. ~~The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it must be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the department for two years from the date the tests were conducted.~~ The control device or alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation

level upon entry must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee or registrant implements continuous surveillance and uses an alarm ratemeter. Records of these tests shall be maintained for inspection by the department for three years from the date the tests were conducted.

11. **Reporting requirements.**

a. In addition to the reporting requirements specified in subsection 5 of section 33-10-04.1-16 and under other sections of this chapter, each licensee or registrant shall provide a written report to the department, within thirty days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable.

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position.

(3) Failure of any component (critical to safe operation of the radiographic exposure device) to properly perform its intended function.

(4) An indicator on a radiation machine fails to show that radiation is being produced, and exposure switch fails to terminate production of radiation when moved to the off position, or a safety interlock fails to terminate x-ray production.

b. The licensee or registrant shall include the following information in each report submitted under subdivision a:

(1) A description of the equipment problem.

(2) Cause of each incident, if known.

(3) Manufacturer ~~and~~, model number, and serial number of equipment involved in the incident.

(4) Place, time, and date of the incident.

(5) Actions taken to establish normal operations.

(6) Corrective actions taken or planned to prevent recurrence.

(7) ~~Qualifications~~ Names and qualifications of personnel involved in the incident.

c. Reports of overexposure submitted under subsection 3 of section 33-10-04.1-16 which involve failure of safety components of radiography equipment must also include the information specified in subdivision b.

d. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of one hundred eighty days in a calendar year, shall notify the department prior to exceeding the one hundred eighty days.

12. **Labeling, storage, and transportation.**

a. The licensee may not use a radiographic exposure device, source changer, or a container to store licensed material unless the radiographic exposure device, source changer, or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple, or black on a yellow background, having a minimum diameter of twenty-five millimeters, and the wording:

CAUTION* - RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")
* or "DANGER"

b. The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in chapter 33-10-13.

c. Locked radiographic exposure devices, radiation machines, source changers, and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

d. The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-05. Personal radiation safety requirements for radiographic personnel.

1. **Conducting industrial radiographic operations.**

   a. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements for and is designated as a radiographer's assistant. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

   b. All radiographic operations conducted at locations of use authorized in the license must be conducted within a permanent radiographic installation, unless specifically authorized by the department.

   c. A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the department, the United States nuclear regulatory commission, or by another agreement state.

   d. Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

2. **Radiation safety officer for industrial radiography.** The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

   a. The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

      (1) Completion of the training and testing requirements of section 33-10-05-05;

      (2) Two thousand hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

      (3) Formal training in the establishment and maintenance of a radiation protection program.

   b. The department will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate experience and

knowledge with respect to the establishment and maintenance of a radiation safety protection program.

c. The specific duties and authorities of the radiation safety officer include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by this article, and reviewing them regularly to ensure that the procedures in use conform to department regulations and to the license or registration conditions;

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by section 33-10-05-05; and

(5) Ensuring that operations are conducted safely and to assume control for instituting corrective actions, including stopping of operations when necessary.

3. **Training and testing.**

a. The licensee or registrant shall not permit any individual to act as a ~~radiographer trainee until such individual has received copies of, instructions in, and has demonstrated an understanding of~~ radiographer's assistant until the individual:

(1) ~~The subjects outlined in appendix A of this chapter~~ Has received copies of and completed a course of at least forty hours on the subjects outlined in appendix A of this chapter, the rules contained in this chapter and in the applicable sections of chapters 33-10-03, 33-10-04.1, and 33-10-10, the applicable United States department of transportation regulations as referenced in chapter 33-10-13, the appropriate department license or certificate of registration; and the licensee's or registrant's operating and emergency procedures. The course shall be one that has been accepted by the department, another state radiation

control agency, or the United States nuclear regulatory commission;

(2) ~~The rules contained in this chapter and in the applicable sections of chapters 33-10-04.1, 33-10-10, and 33-10-13;~~ Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, radiation machines, and radiation survey instruments that the assistant will use;

(3) ~~The appropriate department license or certificate of registration; and~~ Has demonstrated understanding of the instructions provided under paragraph 1 by successfully completing a written test administered by the licensee or registrant on the subjects covered and has demonstrated competence in the use of hardware described in paragraph 2 by successful completion of a practical examination administered by the licensee or registrant on the use of such hardware; and

(4) ~~The~~ Has demonstrated an understanding of the licensee's or registrant's operating and emergency procedures.

b. The licensee or registrant shall not permit any individual to act as a radiographer, as defined in this chapter, unless such individual:

(1) Has met the requirements of subdivision a of subsection ~~1~~ 3;

(2) Has completed at least ~~thirty days of on-the-job training by a radiographer instructor as a radiographer trainee~~ two months of on-the-job training as a radiographer's assistant following completion of the requirements of subdivision a of subsection ~~1~~ 3 (Note: This requirement does not apply to individuals designated as radiographers prior to March 1, 1992.);

(3) Has received training in the use of the licensee's or registrant's radiographic exposure devices, radiation machines, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments;

(4) Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments ~~which~~ that may be employed in industrial radiographic assignments by successful completion of a practical examination administered by the licensee or registrant covering this material;

~~(4) Has demonstrated an understanding of the instructions in subdivision a of subsection 1 by successful completion of a written test and a field examination on the subjects covered; and~~

(5) Has successfully completed, within the last five years, ~~an~~ a radiographer certification examination administered by the department or ~~a third party designated by the department.~~ another certifying entity that affords the same or comparable certification standards of this chapter of the North Dakota radiological health rules; and

(6) Possesses a current ~~identification card issued pursuant to subsection 5 issued by the department or other certifying entity recognized~~ industrial radiographer certification identification card issued pursuant to subsection 7 by the department or other certifying entity that affords the same or comparable certification standards of this chapter of the North Dakota radiological health rules.

c. ~~Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained by the licensee or registrant for inspection by the department for three years following termination of employment.~~ The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed twelve months.

d. ~~Each licensee or registrant shall conduct an internal audit program to ensure that the department's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the department for two years from the date of the audit.~~ Except as provided in paragraph 4, the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer assistant to ensure that regulations, the license or registration requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months.

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation

for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of paragraph 3 of subdivision b and the radiographer's assistant must redemonstrate knowledge of the training requirements of paragraph 2 of subdivision a by a practical examination administered by the licensee or registrant before these individuals can next participate in a radiographic operation.

(3) The department may consider alternatives if the individual serves as both radiographer and radiation safety officer.

(4) If a single individual serves as both radiographer and radiation safety officer and performs all radiography operations, an inspection program is not required.

e. Each licensee shall maintain the following records of training and certification for three years after the record is made:

(1) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

(2) Records of annual refresher safety training and semiannual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any noncompliances observed by the radiation safety officer.

~~2.~~ 4. **Operating and emergency procedures.**

a. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

~~a.~~ (1) The handling and use of sources of radiation for industrial radiography to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in chapter 33-10-04.1.

~~b.~~ (2) Methods and occasions for conducting radiation surveys.

~~e.~~ (3) Methods for posting and controlling access to radiographic areas.

~~d.~~ (4) Methods and occasions for locking and securing sources of radiation.

~~e.~~ (5) Personnel monitoring and the use of personnel monitoring equipment~~, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale~~.

~~f.~~ (6) ~~Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation.~~ Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and controlling of the sealed sources during transportation.

~~g.~~ (7) Minimizing exposure of individuals in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation.

~~h.~~ (8) The procedure for notifying proper personnel in the event of an accident or incident.

~~i.~~ (9) Maintenance of records.

~~j.~~ (10) The inspection ~~and~~, maintenance and operability checks of radiographic exposure devices and associated equipment, ~~source changers~~ survey instruments, alarm ratemeters, transport containers, storage containers, and radiation machines.

(11) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

(12) The procedures for identifying and reporting equipment defects and noncompliant activities.

(13) Source recovery procedures if the licensee will perform source recovery.

b. The licensee or registrant shall maintain copies of current operating and emergency procedures until license or registration termination. Superseded material must be retained for three years after the change has been made.

3. **Personnel monitoring control.**

a. The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer trainee unless, at all times during radiographic operations, each such individual wears a direct-reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to at least fifty-six millionths coulombs per kilogram [200 milliroentgens] and shall be recharged daily or at the start of each shift. Each badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

b. Pocket dosimeters shall be read and exposures recorded at least once daily.

c. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus thirty percent of the true radiation exposure. Records of this check must be maintained for inspection by the department for two years from the date of the annual check for correct response.

d. If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or thermoluminescent dosimeter must be processed immediately. The individual may not return to work with sources of radiation until a determination of the radiation exposure has been made.

e. Reports received from the film badge or thermoluminescent dosimeter processor and records of daily pocket dosimeter readings shall be kept for inspection by the department until the department authorizes disposition.

f. If a film badge or thermoluminescent dosimeter is lost or damaged, the worker shall cease work immediately until a replacement film badge or thermoluminescent dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or thermoluminescent dosimeter.

g. Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

~~(2) Be set to give an alarm signal at a preset dose rate of one hundred twenty-nine millionths coulombs per kilogram [500 milliroentgens] per hour;~~

~~(3) Require special means to change the preset alarm function; and~~

~~(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus twenty percent of the true radiation dose rate.~~

5. **Personnel monitoring.**

a. The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of a direct-reading dosimeter, an operating alarm ratemeter, and an individual monitoring device that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to two millisieverts [200 milliroentgens] and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each individual monitoring device must be assigned to and worn by only one individual.

(3) Individual monitoring devices must be replaced at periods not to exceed one month.

(4) After replacement, each individual monitoring device must be processed as soon as possible.

b. Direct-reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained for inspection by the department for three years from the date of the reading.

c. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed twelve months for correct response to radiation, and records must be maintained for inspection by the department for three years from the date of the

annual response check. Acceptable dosimeters must read within plus or minus twenty percent of the true radiation exposure.

d. If an individual's pocket dosimeter is found to be off-scale or if an individual's electronic personal dosimeter reads greater than two millisieverts [200 milliroentgens], and the possibility of radiation exposure cannot be ruled out as the cause, the individual monitoring device must be sent for processing within twenty-four hours. In addition the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained for inspection by the department until license or registration termination.

e. If the individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged must be included in the records maintained for inspection by the department until license or registration termination.

f. Reports received from the accredited NVLAP individual monitoring device processor must be retained for inspection by the department until license or registration termination.

g. Each alarm ratemeter must:

(1) Be checked, without being exposed to radiation, to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of five mSv per hour [500 mrem per hour] with an accuracy of plus or minus twenty percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed twelve months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations for three years from the date of calibration.

~~4.~~ 6. **Supervision of radiographer ~~trainee~~ assistants.** Whenever a ~~radiographer trainee~~ radiographer's assistant uses sources of

radiation, including radiation machines, radiographic exposure devices, ~~sealed sources~~ associated equipment or related ~~source~~ handling tools, or sealed sources or conducts radiation surveys required by subdivisions b ~~and~~, c, and e of subsection 3 of section 33-10-05-06 to determine that the sealed source has returned to the shielded position or the radiation machine has stopped producing radiation after an exposure, the ~~radiographer trainee~~ radiographer's assistant shall be under the personal supervision of a radiographer ~~instructor~~. The personal supervision must include:

a. The radiographer's physical presence at the site where the sources of radiation are being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the assistant's performance of the operations referred to in this subsection.

~~5.~~ 7. **Identification card.**

a. ~~An~~ A radiographer certification identification card will be issued to each individual who:

(1) Provides the department with documentation showing completion of~~:~~:

(a) The ~~radiographer trainee~~ radiographer's assistant training requirements in subdivision a of subsection ~~1~~ 3.

(b) The radiographer on-the-job training and the demonstration of competence requirements in paragraphs 2, 3, and 4 of subdivision b of subsection ~~1~~ 3.

(2) The requirements in paragraph 1 do not apply to individuals designated as radiographers prior to March 1, 1992.

(3) Has successfully completed, within the last five years, the examination required in paragraph 5 of subdivision b of subsection ~~1~~ 3.

b. Suspension, revocation, or denial. ~~An~~ A radiographer certification identification card may be suspended, revoked, or denied if:

(1) Violations of the requirements of this article are noted~~;~~.

(2) Another certifying entity has revoked, suspended, or denied an identification card for violations of applicable standards.

c. Expiration of the identification card. The identification card will expire five years from the date that the individual successfully completed the examination required in paragraph 5 of subdivision b of subsection ~~4~~ 3.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-06. Precautionary procedures in radiographic operations.

1. **Security.** During each radiographic operation, the radiographer or ~~radiographer trainee shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in chapter 33-10-01, except:~~ other individual present, as required by subsection 1 of section 33-10-05-05, shall maintain continuous direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in chapter 33-10-01, except at permanent radiographic installations where all entry ways are locked and the requirements of subsection 10 of section 33-10-05-04 are met.

   ~~a. Where the high radiation area is equipped with a control device or alarm system as described in subsection 1 of section 33-10-04.1-10.~~

   ~~b. Where the high radiation area is locked to protect against unauthorized or accidental entry.~~

2. **Posting.** ~~Notwithstanding any provisions in subdivision c of subsection 3 of section 33-10-04.1-13, areas in which radiography is being performed shall be conspicuously posted as required by subsection 2 of section 33-10-04.1-13.~~ All areas in which industrial radiography is being performed must be conspicuously posted as required by subsection 2 of section 33-10-04.1-13. Exceptions listed in subsection 3 of section 33-10-04.1-13 do not apply to industrial radiographic operations.

3. **Radiation surveys and survey records.**

   a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in subsection 5 of section 33-10-05-04 is available and used at each site where radiographic exposures are made.

   b. A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be

surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the entire length of the guide tube.

c. A survey must be made of the storage area as defined in section 33-10-05-03 whenever a radiographic exposure device is being placed in storage.

d. A physical radiation survey, as specified in subsection 3 of section 33-10-05-04, shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container, or source changer in a storage area as defined in section 33-10-05-03.

e. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is ~~"off"~~ not producing radiation.

f. All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with subsection 2 of section 33-10-05-06 based on calculated dose rates before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (for example, with the sealed source in the exposed position or when the radiation machine is first energized) to confirm that dose limits are not exceeded.

~~g.~~ Records shall be kept of the surveys required by subdivisions c and d of subsection 3. Such records shall be maintained for inspection by the department for ~~two~~ three years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey must be maintained until the department authorizes their disposition.

4. **Documents and records required at temporary jobsites.** Each licensee or registrant conducting industrial radiography at a temporary jobsite or field station shall have the following records available at that site for inspection by the department:

a. Appropriate license or certificate of registration or equivalent document.

b. Operating and emergency procedures.

c. Applicable rules.

d. Survey records required pursuant to subsection 3 for the period of operation at the site.

e. Daily pocket dosimeter records for the period of operation at the site.

f. The latest instrument calibration and leak test record for specific devices in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter.

g. Utilization records for each radiographic exposure device dispatched from that location.

h. Records of equipment problems identified in daily checks of equipment.

i. Records of alarm system and entrance control checks if applicable.

j. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters or electronic personal dosimeters, or both.

k. The shipping papers for transportation of radioactive material.

l. When operating under reciprocity, a copy of the United States nuclear regulatory commission or agreement state license authorizing the use of radioactive material.

5. **Specific requirements for radiographic personnel performing industrial radiography.**

a. At a jobsite, the following must be supplied by the licensee or registrant:

(1) At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(2) A current whole body ~~personnel monitor (thermoluminescent dosimeter or film badge)~~ individual monitoring device that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor for each individual performing radiographic operations;

(3) An operable, calibrated pocket dosimeter or electronic personal dosimeter with a range of zero to ~~five hundred sixteen ten millionths coulombs per kilogram~~ two millisieverts [200 milliroentgens] for each ~~worker~~ person performing radiographic operations;

(4) An operable, calibrated alarm ratemeter set to give an alarm signal at a preset dose rate of ~~one hundred~~

~~twenty-nine millionths coulombs per kilogram~~ five millisieverts [500 milliroentgens] per hour; and

(5) The appropriate barrier ropes and signs.

(6) Each radiographer must posses a valid industrial radiographer certification identification card, issued by an approved certifying entity.

b. Industrial radiographic operations may not be performed if any of the items specified in subdivision a ~~of subsection 5~~ are not available at the jobsite or are inoperable. Persons performing radiographic operations shall ensure that the items listed in subdivision a and radiation exposure devices and radiation machines are used in accordance with the requirements of this section.

c. Each licensee or registrant shall provide as a minimum two radiographic personnel when sources of radiation are used at temporary jobsites as described in subsection 1 of section 33-10-05-05. ~~If one of the personnel is a radiographer trainee, the other must be a radiographer instructor.~~

d. No individual other than a radiographer or a ~~radiographer trainee who is~~ radiographer's assistant under the personal supervision of a radiographer ~~instructor~~ may manipulate controls or operate equipment used in industrial radiographic operations.

~~e. No individual may act as a radiographer instructor unless such individual:~~

~~(1) Has met the requirements of subdivision b of subsection 1 of section 33-10-05-05;~~

~~(2) Has one year of documented experience as a radiographer; and~~

~~(3) Has been named as a radiographer instructor on the license or registration certificate issued by the department.~~

~~f.~~ e. During an inspection by the department, the department inspector may terminate an operation if any of the items required in subdivision a ~~of subsection 5~~ are not available ~~and~~ or operable, or if the required number of radiographic personnel are not present. Operations may not be resumed until such conditions are met.

6. **Special requirements and exemptions for cabinet radiography.**

a. Systems for cabinet radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this chapter and subsection 1 of section 33-10-04.1-07. If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in paragraph 1. Records of these evaluations shall be maintained for inspection by the department for a period of ~~two~~ three years after the evaluation.

b. Certified cabinet X-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this chapter except that:

(1) Operating personnel must be provided with ~~either a film badge or a thermoluminescent dosimeter~~ a personnel dosimeter that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor and reports of the results must be maintained for inspection by the department.

(2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this paragraph shall be maintained for inspection by the department until disposition is authorized by the department.

(3) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted and recorded in accordance with subsection 10 of section 33-10-05-04.

(4) The registrant shall perform an evaluation at intervals not to exceed one year, to determine conformance with subsection 1 of section 33-10-04.1-07. If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the department for a period of ~~two~~ three years after the evaluation.

c. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the department pursuant to subsection 1 of section 33-10-01-05.

7. **Prohibitions.** Industrial radiography performed with a sealed source which is not fastened to or contained in radiographic exposure devices, known as fishpole radiography, is prohibited unless specifically authorized by the department.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-05-07. Additional recordkeeping requirements.

1. **Records of the specific license for industrial radiography.** Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the department, or until the department terminates the license.

2. **Records of receipt and transfer of sealed sources.**

   a. Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using depleted uranium for shielding and retain each record for three years after it is made.

   b. These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for depleted uranium), and manufacturer, model, and serial number of each sealed source or device, as appropriate.

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

4. **Location of documents and records.**

   a. Each licensee shall maintain copies of records required by this chapter and other applicable chapters of this article at the location specified in paragraph 11 of subdivision a of subsection 3 of section 33-10-03-05.

b. The documents and records required at each field station and each temporary jobsite are specified in subsection 4 of section 33-10-05-06.

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

APPENDIX A
SUBJECTS FOR INSTRUCTION OF ~~RADIOGRAPHER TRAINEES~~ RADIOGRAPHER'S ASSISTANTS

Training provided to qualify individuals as ~~radiographer trainees~~ radiographer's assistants in compliance with subdivision a of subsection ~~1~~ 3 of section 33-10-05-05 shall be presented on a formal basis. The training must include the following subjects:

1. Fundamentals of radiation safety
    a. Characteristics of gamma and X-ray radiation
    b. Units of radiation dose (mrem ~~or~~ and sievert) and quantity of radioactivity (curie ~~or~~ and becquerel)
    c. Significance of radiation dose
        (1) Radiation protection standards
        (2) Biological effects of radiation
        (3) Case histories of radiography accidents
    d. Levels of radiation from ~~sources of radiation~~ licensed material
    e. Methods of controlling radiation dose
        (1) Working time
        (2) Working distances
        (3) Shielding
2. Radiation detection instrumentation to be used
    a. Use of radiation survey instruments
        (1) Operation
        (2) Calibration
        (3) Limitations
    b. Survey techniques
    c. Use of personnel monitoring equipment

(1) ~~Film badges~~ Personnel dosimeters

(2) ~~Thermoluminescent dosimeters (TLD's)~~ Alarming ratemeters

(3) Pocket dosimeters

(4) Other monitoring equipment

3. The requirements of pertinent federal and state rules and regulations

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

5. Radiographic equipment to be used

   a. Remote handling equipment

   b. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails)

   c. Storage and transport containers, source ~~chargers~~ changers

   d. Operation and control of X-ray equipment

   e. Collimators

   f. Storage, control, and disposal of sources of radiation

   g. Inspection and maintenance of equipment

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 2003.

APPENDIX B
RADIOGRAPHER CERTIFICATION

I. **Requirements for an independent certifying organization.** An independent certifying organization shall:

1. Be an organization such as a society or association whose members participate in, or have an interest in, the fields of industrial radiography;

2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin, or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policymaking and decisionmaking review board;

6. Have a set of written organizational bylaws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those bylaws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification, and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed

by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the department, the United States nuclear regulatory commission, and other independent certifying organizations or agreement states, or both, and allow periodic review of its certification program and related records; and

13. Provide a description to the department of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. **Requirements for certification programs.** All certification programs must:

1. Require applicants for certification to receive training in the topics set forth in appendix A or equivalent United States nuclear regulatory commission or agreement state regulations and satisfactorily complete a written examination covering these topics;

2. Require applicants for certification to provide documentation that demonstrates that the applicant has received training in the topics set forth in appendix A or equivalent United States nuclear regulatory commission or agreement state regulations, satisfactorily completed a minimum period of on-the-job training, and has received verification by an agreement state or a United States nuclear regulatory commission licensee that the applicant has demonstrated the capability of independently working as a radiographer;

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application, revoking, suspending, and reinstating a certificate;

5. Provide a certification period of not less than three years nor more than five years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. **Requirements for written examinations.** All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in appendix A or equivalent agreement state requirements;

2. Written in a multiple-choice format; and

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in appendix A.

History: Effective March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-10.1-03, 23-10.1-04

CHAPTER 33-10-06

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

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

33-10-06-02. Definitions. As used in this chapter, the following definitions apply:

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

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

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

4. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is ninety-nine percent minimum aluminum, twelve-hundredths percent copper.)

~~4.~~ 5. "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

~~5.~~ 6. "Attenuation block" means a block or stack, having dimensions twenty centimeters by twenty centimeters by three and eight-tenths centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

~~6.~~ 7. "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a

preselected location or locations a required quantity of radiation (includes devices such as phototimers and ion chambers).

~~7.~~ 8. "Barrier" (see "protective barrier").

~~8.~~ 9. "Beam axis" means a line from the source through the centers of the X-ray fields.

~~9.~~ 10. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the X-ray field.

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

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

~~10.~~ 13. ~~"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.~~ "Bone densitometry system" means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

~~11.~~ 14. "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

~~12.~~ 15. "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

~~13.~~ 16. "Certified components" means components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 [Pub. L. 90-602].

~~14.~~ 17. "Certified system" means any X-ray system which has one or more certified component or components.

~~15.~~ 18. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

~~16.~~ 19. "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a ~~population~~ set of observations. It is estimated using the following equation:

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

where:

s = Estimated standard deviation of the population.

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

X_i = i^{th} observation in sample.

n = Number of observations in sample.

~~17.~~ 20. "Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

~~18.~~ 21. "Contact therapy system" means an X-ray system used for therapy with the X-ray tube port placed in contact with or within five centimeters of the surface being treated.

~~19.~~ 22. "Control panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

~~20.~~ 23. "Cooling curve" means the graphical relationship between heat units stored and cooling time.

~~21.~~ 24. "CT" (see "computed tomography").

~~22.~~ 25. "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

~~23.~~ 26. "Detector" (see "radiation detector").

~~24.~~ 27. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

~~25.~~ 28. "Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission, and reception of X-rays and the transformation, storage, and visual display of the resultant X-ray image.

~~26.~~ 29. "Diagnostic X-ray system" means an X-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

~~27.~~ 30. "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "scattered radiation").

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

~~28.~~ 32. "Entrance ~~radiation~~ exposure rate" means the radiation exposure free in air per unit time at the point where the center of the useful beam enters the patient.

~~29.~~ 33. "Equipment" (see "X-ray equipment").

~~30.~~ 34. "Field emission equipment" means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

~~31.~~ 35. "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

~~32.~~ 36. "Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a ~~fluoroscopic~~ visible image. It includes the image receptor or receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

~~33.~~ 37. "Focal spot ~~(actual)~~" means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

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

~~34.~~ 39. "General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

~~35.~~ 40. "Gonad shield" means a protective barrier for the testes or ovaries.

~~36.~~ 41. "Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the radiation exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

~~37.~~ 42. "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.

~~38.~~ 43. "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x seconds.

~~39.~~ 44. "HVL" (see "half-value layer").

~~40.~~ 45. "Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

~~41.~~ 46. "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

~~42.~~ 47. "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during a mammographic examination.

~~43.~~ 48. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

~~44.~~ 49. "Irradiation" means the exposure of matter to ionizing radiation.

~~45.~~ 50. "Kilovolts peak" (see "peak tube potential").

~~46.~~ 51. "kV" means kilovolts.

~~47.~~ 52. "kVp" (see "peak tube potential").

~~48.~~ 53. "kWs" means kilowatt second. It is equivalent to 10^3 kV · mA · s, i.e.,

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

~~49.~~ 54. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

~~50.~~ 55. "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

a. The useful beam~~.~~; and

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

~~51.~~ 56. "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, i.e., ten milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

~~52.~~ 57. "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

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

~~53.~~ 59. "Linear attenuation coefficient" or "u" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

~~54. "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:~~

~~$$\text{Percent line-voltage regulation} = 100\ (V_n - V_T)\ / V_T$$~~

~~where:~~
~~V_n = No-load line potential and~~
~~V_T = Load line potential~~

~~55.~~ 60. "mA" ~~(see~~ means milliampere~~)~~.

~~56.~~ 61. "mAs" ~~(see~~ means milliampere second~~)~~.

~~57. "Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.~~

~~58.~~ 62. "Milliampere" as used in this chapter applies to X-ray tube current.

~~59.~~ 63. "Milliampere second" as used in this chapter is the product of the tube current and X-ray exposure time measured in seconds.

~~60.~~ 64. "Mobile X-ray equipment" (see "X-ray equipment").

~~61.~~ 65. "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

~~62.~~ 66. "PBL" has the same meaning as "positive beam limitation".

~~63.~~ 67. "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

~~64.~~ 68. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

~~65.~~ 69. "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated (see "automatic exposure control").

~~66.~~ 70. "PID" has the same meaning as "position indicating device".

~~67.~~ 71. "Portable X-ray equipment" (see "X-ray equipment").

~~68.~~ 72. "Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

~~69.~~ 73. "Positive beam limitation" means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

~~70.~~ 74. "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

~~71.~~ 75. "Primary protective barrier" (see "protective barrier").

~~72.~~ 76. "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

~~73.~~ 77. "Protective barrier" means a barrier of radiation absorbing material or materials used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam; and

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

~~74.~~ 78. "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

~~75.~~ 79. "Qualified expert" means an individual having the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American board of radiology, or the American board of health physics, or the American board of medical physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, "qualified expert" means an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in therapeutic radiological physics or X-ray and radium physics by the American board of radiology, or those having equivalent qualifications.

~~76.~~ 80. "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

~~77.~~ 81. "Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

~~78.~~ 82. "Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

~~79.~~ 83. "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

~~80.~~ 84. "Radiological physicist" means an individual who:

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

b. Has a bachelor's degree in one of the physical sciences or engineering and three year's full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American board of radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

c. Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

~~81.~~ 85. "Rating" means the operating limits as specified by the component manufacturer.

~~82.~~ 86. "Recording" means producing a permanent form of an image resulting from X-ray photons.

~~83.~~ 87. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (see "direct scattered radiation").

~~84.~~ 88. "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

~~85.~~ 89. "Secondary protective barrier" (see "protective barrier").

~~86.~~ 90. "Shutter" means a device attached to the tube housing assembly which can ~~totally~~ intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

~~87.~~ 91. "SID" has the same meaning as "source-image receptor distance".

~~88.~~ 92. "Source" means the focal spot ~~(actual)~~ of the X-ray tube.

~~89.~~ 93. "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

~~90.~~ 94. "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

~~91.~~ 95. "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

~~92.~~ 96. "Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

~~93.~~ 97. "SSD" means the distance between the source and the skin entrance plane of the patient.

~~94.~~ 98. "Stationary X-ray equipment" (see "X-ray equipment").

~~95.~~ 99. "Stray radiation" means the sum of leakage and scattered radiation.

~~96.~~ 100. "Technique factors" means the conditions of operation. They are specified as follows:

a. For capacitor energy storage equipment, peak tube potential in kilovolts and quantity of charge in milliampere second.

b. For field emission equipment rated for pulsed operation, peak tube potential in kilovolts and number of X-ray pulses.

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kilovolts, scan time in seconds, and either tube current in milliampere, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in milliampere second.

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kilovolts, and either tube current in milliampere and scan time in seconds, or the product of tube current and exposure time in milliampere second and the scan time when the scan time and exposure time are equivalent.

e. For all other equipment, peak tube potential in kilovolt and either tube current in milliampere and exposure time in seconds, or the product of tube current and exposure time in milliampere second.

~~97.~~ 101. "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

~~98.~~ 102. "Tomogram" means the depiction of X-ray attenuation properties of a section through the body.

~~99.~~ 103. "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

~~100.~~ 104. "Tube" means an X-ray tube, unless otherwise specified.

~~101.~~ 105. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

~~102.~~ 106. "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

~~103.~~ 107. "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

~~104.~~ 108. "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given source-image receptor distance.

~~105.~~ 109. "Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

~~106.~~ 110. "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

~~107.~~ 111. "X-ray exposure control" means a device, switch, button, or other similar means by which the operator initiates or terminates, or both, the radiation exposure. It may include equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices.

~~108.~~ 112. "X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.

c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.

~~109.~~ "X-ray field" means that area of the intersection of the useful beam and
113. any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the radiation exposure rate is one-fourth of the maximum in the intersection.

~~110.~~ "X-ray high-voltage generator" means a device which transforms
114. electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube, high-voltage switches, electrical protective devices, and other appropriate elements.

~~111. "X-ray subsystem" means any combination of two or more components of an X-ray system.~~

~~112.~~ "X-ray system" means an assemblage of components for the
115. controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

~~113.~~ "X-ray tube" means any electron tube which is designed ~~to be used primarily for the production of X-rays~~ for the conversion of electrical
116. energy into X-ray energy.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-03. General requirements.

1. **Administrative controls.**

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

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

      (2) ~~Individuals who will be~~ All individuals, except those listed in part 1 of appendix G, prior to operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment commensurate with the size, scope, and nature

of the service. ~~As a minimum, individuals shall be instructed in and demonstrate competence in subjects outlined in appendix F of this chapter.~~ In addition, all individuals shall meet the specific requirements as outlined in subparagraph a or b. The department may use interview, observation, or testing~~, or both,~~ to determine compliance. Records must be maintained by the registrant to demonstrate compliance with this paragraph.

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

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

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

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

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

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

[1] Limited diagnostic operators shall have successfully completed the course of training required by one of the allied health professions listed in part 2 of appendix G;

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

[3] Complete the three-hour self-study course designed by the state health department; and

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

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

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

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

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

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

[2] When a practice requires a specific view or examination outside the scope of practice listed in appendix I to be conducted on a routine basis, and the facility has only limited diagnostic operators, application may be made to the department requesting approval for a limited diagnostic operator to perform the procedure. This allowance shall be limited to the facility, the specific individual, and the procedure requested. After an allowance has been granted, reapplication and reauthorization are not necessary for the same procedure. The application for allowance should include the following:

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

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

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

(d) Limited diagnostic operator implementation period.

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

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

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

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

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

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

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

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

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel, which specifies for all examinations performed with that system the following information:

(a) Patient's body part and anatomical size or body thickness, or age (for pediatrics), versus technique factors to be utilized.

(b) Type and size of the film or film-screen combination to be used.

(c) Type and focal distance of the grid to be used, if any.

(d) Source-image receptor distance to be used (except for dental intraoral radiography).

(e) Type and location of placement of gonad shielding to be used.

(f) For mammography, indication of kVp/target/filter combination.

(4) The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding restrictions and any restrictions of the operating technique required for the safe operation of the particular

X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

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

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

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

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

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

(7) Individuals may not be exposed to the useful beam except for healing arts purposes and when such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(a) Exposure of an individual for training, demonstration, or other non-healing-arts purposes.

(b) Exposure of an individual for the purpose of healing arts screening except as authorized by paragraph 11.

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The safety rules, required by this section shall list individual projections where holding devices cannot be utilized.

(b) Written safety procedures, as required by paragraph 4, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(c) The human holder shall be instructed in personal radiation safety and protected as required by paragraph 5.

(d) No individual shall be used routinely to hold film or patients.

(e) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five-tenths millimeter lead equivalent material.

(f) A record shall be made of the examination and shall include the name of the human holder, date of the examination, number of exposures, and technique factors utilized for the exposure.

(g) Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

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

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

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

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

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

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

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

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

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

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of section 33-10-04.1-06, "Occupational dose limits". In addition:

(a) When protective clothing or devices are worn on portions of the body and a monitoring device is required, at least one such monitoring device shall be utilized as follows:

[1] When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

[2] The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by subsection 7 of section 33-10-04.1-15. If more than one device is used and a record is made of

the data, each dose shall be identified with the area where the device was worn on the body.

(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the department. When requesting such approval, that person shall submit the information outlined in appendix E ~~of this chapter~~. If any information submitted to the department becomes invalid or outdated, the department shall be immediately notified.

b. Information and maintenance record and associated information. The registrant shall maintain the following information for each X-ray system for inspection by the department:

(1) Maximum rating of technique factors.

(2) Model and serial numbers of all ~~certifiable~~ major components and user's manuals for those components.

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

(4) Tube rating charts and cooling curves.

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

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

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

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

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

c. X-ray log.

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

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

2. **Plan review.**

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

b. The department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

c. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in sections 33-10-04.1-06 and 33-10-04.1-07.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-04. General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

1. **Warning label.** The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. **Battery charge indicator.** On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. **Leakage radiation from the diagnostic source assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed one hundred milliroentgens in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

4. **Radiation from components other than the diagnostic source assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

5. **Beam quality.**

   a. Half-value layer.

      (1) The half-value layer (HVL) of the useful beam for a given X-ray tube potential shall not be less than the values shown in table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts Peak)	Half-Value Layer In Millimeters Aluminum	
		Dental Intraoral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3

	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

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

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

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

HVL> (kVp/100) mmAl and < (kVp/100) + 0.1 mmAl
= =

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

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

7. **Mechanical support of tube head.** The tube housing assembly supports shall be adjusted such that the tube housing assembly will

remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

8. **Technique indicators.**

   a. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

   b. The requirements of subdivision a may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the ~~operators~~ operator's position except in the case of spot films made by the fluoroscopist.

9. **Maintaining compliance.** Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the federal X-ray equipment performance standard (21 CFR part 1020) shall be maintained in compliance with applicable requirements of that standard.

10. **Locks.** All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.

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

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

1. **Limitation of useful beam.**

   a. Primary barrier.

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

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

   b. X-ray field.

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

(2) For uncertified fluoroscopic systems with a spot-film device, the X-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot-film size for which the device is designed. Measurements shall be made at the ~~minimum~~ maximum source image distance available but at no less than twenty centimeters tabletop to the film plane distance.

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

(4) Other requirements for fluoroscopic beam limitation:

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

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

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

(d) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For noncircular X-ray fields used with

circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

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

(a) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

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

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

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

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

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

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

(b) Must incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden.

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

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

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

3. **Radiation exposure rate limits.**

a. Entrance ~~radiation~~ exposure rate allowable limits.

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

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

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

[1] When the high level control is activated, the equipment shall not be operable at any

combination of tube potential and current that will result in an exposure rate in excess of five and sixteen hundredths millicoulomb per kilogram [20 roentgens] per minute at the point where the center of the useful beam enters the patient.

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

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

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

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

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

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

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

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

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

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

(c) If the source is above the table, the radiation exposure rate shall be measured at thirty centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

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

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

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

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

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

the date the measurements were performed shall be included in the results.

(c) Conditions of periodic measurements of typical entrance ~~radiation~~ exposure rate are as follows:

[1] The measurement shall be made under the conditions that satisfy the requirements of paragraph 4.

[2] The kilovolts peak, mA, and other selectable parameters shall be the settings typical of clinical use on a ~~23 cm~~ twenty-three centimeters thick abdominal patient.

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

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

(d) Conditions of periodic measurements of maximum entrance ~~radiation~~ exposure rate are as follows:

[1] The measurement shall be made under the conditions that satisfy the requirements of paragraph 3.

[2] The kVp, mA, and other selectable parameters shall be the maximum selectable parameters of clinical use of the X-ray system.

[3] The X-ray systems that incorporate automatic ~~radiation~~ exposure control shall have sufficient material placed in the useful beam to produce a kVp, mA, and other selectable parameters to satisfy the conditions of item 2 ~~of subparagraph d of this paragraph~~.

[4] X-ray systems that do not incorporate an automatic ~~radiation~~ exposure control shall utilize

the maximum kVp, mA, and other selectable parameters of clinical use of the X-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

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

   a. The radiation exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, shall not exceed five hundred sixteen thousandths microcoulomb per kilogram [2 milliroentgens] per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen (C/kg) per minute of entrance ~~radiation~~ exposure rate.

   b. Measuring compliance of barrier transmission.

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

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

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

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

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

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

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

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

c. Thirty centimeters on all mobile fluoroscopes.

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

7. **Fluoroscopic timer.**

a. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

8. **Control of scattered radiation.**

a. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than twenty-five one-hundredths millimeter lead equivalent.

b. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(1) Is at least one hundred twenty centimeters from the center of the useful beam; or

(2) The radiation has passed through not less than twenty-five one-hundredths millimeter lead equivalent material, including, but not limited to, drapes, bucky-slot cover-sliding or folding panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in paragraph 5 of subdivision a of subsection 1 of section 33-10-06-03.

c. The department may grant exceptions to subdivision b of this subsection in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.

9. **Spot-film exposure reproducibility.** Fluoroscopic systems equipped with spot-film mode shall meet the exposure reproducibility requirements of subsection 5 of section 33-10-06-06 when operating in the spot-film mode.

10. **Radiation therapy simulation system.** Radiation therapy simulation systems shall be exempt from all the requirements of subsections 1, 3, 4, and 7 of section 33-10-06-05 provided that:

    a. Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

    b. Such systems as do not meet the requirements of subsection 7 of section 33-10-06-05 are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

11. **Structural shielding requirements** (see appendix E).

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

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

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

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

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

(3) The department may grant an exemption to paragraphs 1 and 2 ~~of this subdivision~~ on noncertified X-ray systems, provided the registrant makes a written application for such exemption and demonstrates in the application:

(a) That it is impractical to comply with paragraphs 1 and 2 ~~of this subdivision~~; and

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

b. Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of subdivision a ~~of this subsection~~, all stationary X-ray systems both certified and noncertified shall meet the following requirements:

(1) Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent of the source-image receptor distance, and to indicate the source-image receptor distance to within two percent.

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.

(3) Indication of field size dimensions and source-image receptor ~~distance's~~ distances shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the source-image receptor distance when the beam axis is indicated to be perpendicular to the plane of the image receptor.

c. X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at the fixed source-image receptor distance shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within two percent of the source-image receptor distance, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

d. Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for

mammography shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated source-image receptor distance except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than two percent of the source-image receptor distance. This requirement can be met with a system which performs as prescribed in paragraph 3 of subdivision e ~~of this subsection~~. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the source-image receptor distance may vary, the source-image receptor distance indication specified in subparagraphs a and b of paragraph 3 of subdivision e ~~of this subsection~~ shall be the maximum source-image receptor distance for which beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

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

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

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

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

(a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the

requirement for each combination of image receptor size and source-image receptor distance for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and source-image receptor distance for which it is designed; or

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

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

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

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

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

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

Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.

b. Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of subdivision a of subsection 1 and subdivision a of this subsection ~~2 of this section~~.

c. Beam limitation and alignment on stationary general purpose X-ray systems equipped with positive beam limitation (PBL). The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of this subdivision have been properly used.

(1) Positive beam limitation (PBL), when provided, shall function as described in paragraph 2 whenever all of the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder.

(b) The image receptor length and width are each less than fifty centimeters.

(c) The X-ray beam axis is within plus or minus three degrees of vertical and the source-image receptor distance is ninety centimeters to one hundred thirty centimeters inclusive~~;~~, or the X-ray beam axis is within plus or minus three degrees of horizontal and the source-image receptor distance is ninety centimeters to two hundred five centimeters inclusive.

(d) The X-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus three degrees.

(e) Neither tomographic nor steroscopic radiography is being performed.

(f) The positive beam limitation system has not been intentionally overridden. The override provision is subject to paragraph 3.

(2) Positive beam limitation (PBL), when provided, shall prevent the production of X-rays when:

(a) Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by paragraph 5, from the corresponding image

receptor dimensions by more than three percent of the source-image receptor distance.

(b) The sum of the length and width differences as stated in subparagraph a, without regard to sign, exceeds four percent of the source-image receptor distance.

(c) The beam-limiting device is at a source-image receptor distance for which positive beam limitation (PBL) is not designed for sizing.

(3) If a means of overriding the positive beam limitation (PBL) system exists, that method:

(a) If located in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator.

[1] Must require that a key be utilized to defeat the positive beam limitation;

[2] Must require that the key remain in place during the entire time the positive beam limitation system is overridden; and

[3] Must require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION
SYSTEM FAILURE

(b) Must include a label visible to the operator that override of the positive beam limitation system is engaged.

(4) Compliance with paragraph 2 must be determined when the requirements of paragraph 1 are met. Compliance must be determined no sooner than five seconds after insertion of the image receptor.

(5) The positive beam limitation system must be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at the source-image receptor distance of one hundred centimeters must be equal to or less than five centimeters by five centimeters.

(6) The positive beam limitation system must be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in paragraph 2, then any change of image receptor size or source-image receptor distance must cause the automatic return.

3. **Radiation exposure control.**

a. Exposure initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

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

c. Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero". <u>It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.</u>

(1) Manual exposure control. An X-ray control which shall be the equivalent of a dead-man switch shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:

(a) Exposure of one-half second or less; or

(b) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(2) Automatic exposure controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the X-ray tube potential is equal to or greater than fifty kVp, the minimum exposure time for field emission

equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(c) The minimum exposure time for all equipment other than that specified in subparagraph b shall be equal to or less than one-sixtieth second or a time interval required to deliver five mAs, whichever is greater;

(d) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than six hundred mAs per exposure except that, when the X-ray tube potential is less than fifty kVp, the product of X-ray tube current and exposure time shall be limited to not more than two thousand mAs per exposure; and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph d, and manual resetting shall be required before further automatically timed exposures can be made.

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

$$(X_1 - X_2) < 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

e. Exposure control location. The X-ray exposure control shall be so placed that the operator can view the patient while making ~~exposure~~ exposures (see appendix B).

f. Operator protection, except veterinary systems.

(1) Stationary systems. Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure (see appendix B).

(2) Mobile and portable systems. Mobile and portable X-ray systems which are:

(a) Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph 1 ~~of subdivision f~~; and

(b) Used for less than one week at the same location shall be provided with either a protective barrier at least two meters [6.5 feet] high for operator protection during exposures, or means shall be provided to allow the operator to be at least two and seven-tenths meters [9 feet] from the tube housing assembly during the exposure.

(3) Mammography systems shall be operable from a shielded position.

g. Operator protection for veterinary systems. All stationary, mobile, or portable X-ray systems used for veterinary work shall be provided with either a two-meter [6.5-foot] high protection barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least two and seven-tenths meters [9 feet] from the tube housing assembly during exposures.

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

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

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

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

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

specifications, the deviation shall not exceed ten percent of the indicated value for kVp and twenty percent for time.

8. **mA/mAs linearity.** The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rated:

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

   $$X_1 - X_2 < 0.10 (X_1 + X_2)$$

   where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

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

   $$X_1 - X_2 < 0.10 (X_1 + X_2)$$

   where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provided continuous selection.

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

9. **Other requirements:**

a. Transmission limit for image receptor supporting devices used for mammography. For X-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beams through the image receptor support provided with the system will be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed twenty-five and eight-tenths microcoulomb per kilogram [.01 milliroentgen] for each activation of the tube. Exposure shall be measured with the system operated at the minimum source-image receptor distance for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (milliampere second) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

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

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20-04, 23-20.1-03, 23-20.1-04

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

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

   a. Eighteen centimeters if operable above fifty kilovolts peak.

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

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

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

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

3. **Radiation exposure control.**

a. Exposure initiation.

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

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

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

c. Exposure termination.

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

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

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

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

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

where X_1 and X_2 are the average values.

e. Exposure control location and operator protection.

(1) Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure and so the operator can view the patient while making the exposure.

(2) Mobile and portable X-ray systems which are:

(a) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph 1 ~~of this subdivision~~.

(b) Used for less than one week in the same location shall be provided with either a protective barrier at least two meters [6.5 feet] high for operator protection, or means to allow the operator to be at least two and seven-tenths meters [9 feet] from the tube housing assembly while making exposures.

4. **Reproducibility.** When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than five hundredths for any specific combination of selected technique factors.

5. **mA/mAs linearity.** The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of forty percent to one hundred percent of the maximum rated.

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

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

where X_1 and X_2 are the average values obtained at any two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

b. Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of coulombs per kilogram per milliampere second (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than ten hundredths times their sum:

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

where X_1 and X_2 are the average values obtained by any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

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

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

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

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

9. **Administrative controls.**

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

b. The tube housing and the position indicating device shall not be handheld during an exposure.

c. The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subdivision a of subsection 2 ~~of this section~~.

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

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

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; July 1, 1995; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

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

1. **Equipment requirements.**

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

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

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

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

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

b. Permanent beam-limiting devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same

or higher degree of protection as required by the tube housing assembly.

c. Removable and adjustable beam-limiting devices.

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

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

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

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

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

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

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

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

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

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

h. Beam monitor system. Systems of greater than one hundred fifty kilovolts peak manufactured after October 1, 1982, shall be provided with a beam monitor system which:

(1) Shall have the detector of the monitor system interlocked to prevent incorrect positioning in the useful beam;

(2) Shall not allow irradiation until a preselected number of roentgens has been made at the treatment control panel;

(3) Shall independently terminate irradiation when the preselection number of roentgens has been reached;

(4) Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

(5) Shall have a display at the control panel from which the dose at a reference point in the treatment volume can be calculated;

(6) Shall have a control panel display which maintains the reading until intentionally reset to zero; and

(7) Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

i. Timer.

(1) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(3) The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.

(4) The timer shall permit accurate presetting and determination of exposure times as short as one second.

(5) The timer shall not permit an exposure if set at zero.

(6) The timer shall not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

j. Control panel functions. The control panel, in addition to the displays required in other requirements of this section, shall have:

(1) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

(2) An indication of whether X-rays are being produced;

(3) Means for indicating kilovolts and X-ray tube current;

(4) The means for terminating an exposure at any time;

(5) A locking device which will prevent unauthorized use of the X-ray system; and

(6) For X-ray equipment manufactured after October 1, 1982, a positive display of specific filters in the beam.

k. Multiple tubes. When a control panel may energize more than one X-ray tube:

(1) It shall be possible to activate only one X-ray tube at any time;

(2) There shall be an indication at the control panel identifying which X-ray tube is energized; and

(3) There shall be an indication at the tube housing assembly when that tube is energized.

l. Source-to-skin distance. There shall be means of determining the source-to-skin distance to within one centimeter.

m. Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

(2) An indication of shutter position shall appear at the control panel.

n. Low filtration X-ray tubes. Each X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

2. **Facility design requirements for systems capable of operating above fifty kilovolts peak.**

a. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

b. Viewing systems.

(1) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(2) When the primary viewing system is by electronic means, television, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

c. Additional requirements for X-ray systems capable of operation above one hundred fifty kilovolts peak.

(1) All protective barriers must be fixed except for entrance doors or beam interceptors.

(2) The control panel shall be outside the treatment room.

(3) Entrance interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(4) When any door referred to in paragraph 3 ~~of this subdivision~~ is opened while the X-ray tube is activated, the radiation exposure at a distance of one meter from the source must be reduced to less than twenty-five and eight-tenths microcoulomb per kilogram [100 milliroentgens] per hour.

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

a. Surveys.

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

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

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

b. Calibration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) Records of spot check measurements shall be maintained by the registrant for two years after completion of the spot check measurements and any necessary corrective actions.

(7) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 3 of section

33-10-06-08 or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

(1) X-ray systems shall not be left unattended unless the system is secured against unauthorized use.

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(3) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed fifty kilovolts peak. In such cases, the holder shall wear protective gloves and apron of not less than five-tenths millimeter lead equivalency at one hundred kilovolts peak.

(4) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of section 33-10-04.1-06. No individual other than the patient shall be in the treatment room during exposures when the kilovolts peak exceeds one hundred fifty.

(5) The X-ray system shall not be used in the administration of radiation therapy unless the requirements of subdivision b ~~of this subsection~~ and paragraph 4 of subdivision c have been met.

History: Amended effective October 1, 1982; June 1, 1986; June 1,1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-09. X-ray and electron therapy systems with energies of one megaelectronvolt (MeV) and above. Chapter 33-10-09 except subdivisions c and d of subsection 7 of section 33-10-09-03 shall apply to medical facilities using therapy systems with energies one megaelectronvolt and above.

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

a. "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam-limiting device.

b. "Beam scattering filter" means a filter used in order to scatter a beam of electrons.

c. "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

d. ~~"Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.~~ "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

e. ~~"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.~~ "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

f. "Existing equipment" means therapy systems subject to this section which were manufactured on or before January 1, 1985.

g. "Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

h. "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the fifty percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

i. "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

j. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

k. "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

l. "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

m. "New equipment" means systems subject to this section which were manufactured after January 1, 1985.

n. "Normal treatment distance" means:

(1) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) For X-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

o. "Radiation head" means the structure from which the useful beam emerges.

p. "Shadow tray" means a device attached to the radiation head to support auxiliary beam-limiting material.

q. "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and patient during radiation.

r. "Target" means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

s. "Virtual source" means a point from which radiation appears to originate.

2. **Requirements for equipment.**

a. Leakage radiation to the patient area.

(1) New equipment shall meet the following requirements:

(a) For all operating conditions producing maximum leakage, the absorbed dose in rads [grays] due to leakage radiation, including X-rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or the normal treatment distance and outside the maximum useful beam, shall not exceed one-tenth percent of the maximum absorbed dose in rads [grays] of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters at the positions specified. Measurements of the portion of the leakage radiation

dose contributed by neutrons shall be averaged over an area up to but not exceeding two hundred square centimeters.

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

(2) Existing equipment shall meet the following requirements:

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

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

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

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

(2) The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in paragraph 1 ~~of this subdivision~~ for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified. Neutron measurements shall be averaged over an area up to but not exceeding two hundred square centimeters.

c. Beam-limiting devices. Adjustable or interchangeable beam-limiting devices shall be provided and such devices shall transmit no more than two percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

d. Filters.

(1) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(2) If the absorbed dose rate data required by subdivision p of subsection 2 of section 33-10-06-04 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

(3) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(a) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) A display shall be provided at the treatment control panel showing the filters in use; and

(d) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

e. Beam quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

(1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the value stated in table III. Linear interpolation shall be used for values not stated.

TABLE III

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

(2) Compliance with paragraph 1 ~~of this subdivision~~ shall be determined using:

(a) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

(b) The largest field size available which does not exceed fifteen centimeters by fifteen centimeters; and

(c) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.

(3) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during X-ray irradiation, shall not exceed the limits stated in table IV. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60

15	0.50
35	0.40
50	0.20

(4) Compliance with paragraph 3 ~~of this subdivision~~ shall be determined by measurements made:

(a) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

(b) Using a phantom whose size and placement meet the requirements of paragraph 2 ~~of this subdivision~~;

(c) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

(d) The largest field size available which does not exceed fifteen centimeters by fifteen centimeters.

(5) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to stray neutrons, excluding stray neutron radiation, for specified operating conditions.

f. Beam monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

(1) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

(2) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

(3) The detectors and system into which the detector is incorporated shall meet the following requirements:

(a) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

(b) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(c) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(d) For new equipment, the design of the dose monitoring systems shall assure that:

[1] The malfunctioning of one system does not affect the correct functioning of the second system; and

[2] The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

(e) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

[1] Maintain a reading until intentionally reset to zero;

[2] Have only one scale and no scale multiplying factors;

[3] Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

[4] In the event of power failure, the dose monitoring information required in this subparagraph displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty-minute period of time.

g. Beam symmetry. In new equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions must be monitored before the beam passes through the beam-limiting device. Facilities must be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ten percent, the irradiation is terminated.

h. Selection and display of dose monitor units.

(1) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(2) After useful beam termination, it shall be necessary to reset the dosimeter display to zero before treatment can be reinitiated.

(3) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(4) For new equipment after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

i. Termination of irradiation by the dose monitoring system or systems during stationary beam therapy.

(1) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(2) If original design of the equipment included a second dose monitoring system, that system must be capable of terminating irradiation when not more than fifteen percent or forty dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring.

(3) For new equipment, a second dose monitoring system must be present. That system must be capable of terminating irradiation when not more than ten percent or twenty-five dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(4) For new equipment, an indicator on the control panel must show which dose monitoring system has terminated irradiation.

j. Interruption switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

k. Termination switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

l. Timer.

(1) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and decimals of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(3) For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

(4) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitor systems have not previously terminated irradiation.

m. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

(2) An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(4) An interlock system shall be provided to prevent irradiation with X-rays except to obtain a port film when electron applicators are fitted.

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted.

(6) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

n. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

(2) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(3) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

(4) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the X-ray target or electron window deviates by more than twenty percent or three megaelectron volts, whichever is smaller, from the selected nominal energy.

o. Selection of stationary beam therapy or moving beam therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

(2) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(4) The mode of operation shall be displayed at the treatment control panel.

(5) For new equipment, an interlock system shall be provided to terminate irradiation if:

(a) Movement of the gantry occurs during stationary beam therapy; or

(b) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

(6) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(a) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than twenty percent from the selected value.

(b) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.

(7) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by subsection 1 ~~of this section~~.

p. Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated (the radiation detectors specified in subdivision f of subsection 2 of section 33-10-06-09 may form part of this system). In addition:

(1) The dose monitor unit rate shall be displayed at the treatment control panel.

(2) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be a record maintained by the registrant.

q. Location of virtual source and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

(1) The X-ray target or the virtual source of X-rays.

(2) The electron window or the virtual source of electrons if the system has electron beam capabilities.

r. System checking facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

3. Facility and shielding requirements. In addition to chapter 33-10-04.1, the following design requirements shall apply:

   a. Protective barriers. All protective barriers must be fixed except for entrance doors or beam interceptors.

   b. Control panel. The control panel must be located outside the treatment room.

   c. Viewing systems.

      (1) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel.

      (2) When the viewing system is by electronic means an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary system.

   d. Aural communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

   e. Room entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".

   f. Entrance interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating exposure by manual action at the control panel.

4. Surveys, calibrations, spot checks, and operating procedures.

a. Surveys.

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

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

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

b. Calibrations.

(1) The calibration of systems subject to section 33-10-06-09 shall be performed in accordance with an established calibration protocol acceptable to the department (The calibration protocol published by the American association of physicists in medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the department for concurrence that the protocol is acceptable.) before the system is first used for irradiation of patient and thereafter at time intervals which do not exceed twelve months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

(2) The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.

(3) Calibration radiation measurements required by paragraph 1 must be performed using a dosimetry system:

(a) Having a calibration factor for cobalt-60 gamma rays traceable to a national standard.

(b) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration.

(c) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system.

(d) Which has had constancy checks performed on the system as specified by a radiological physicist.

(4) Calibrations must be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

(5) The calibration of the therapy beam shall include but be not limited to the following determinations:

(a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the sidelight and back-pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths.

(b) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

(c) The uniformity of the radiation field and any dependency upon the direction of the useful beam.

(d) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(e) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

(6) Records of the calibration performed pursuant to paragraph 1 ~~of this subdivision~~ shall be maintained by the registrant for five years after completion of the full calibration.

(7) A copy of the latest calibration performed pursuant to paragraph 1 ~~of this subdivision~~ shall be available in the area of the control panel.

c. Spot checks. Spot checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:

(1) The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the

procedure shall be submitted to the department prior to its implementation.

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

(3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

(4) At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.

(5) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement may not be utilized as a spot check measurement.

(6) The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

(7) Whenever a spot check indicates a significant change in operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated as required in subdivision b of subsection 4 ~~of this section~~.

(8) Records of spot check measurements shall be maintained by the registrant for a period of two years after completion of the spot check measurements and any necessary corrective actions.

(9) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of subdivision b of subsection 4 ~~of this section~~ or which has been intercompared with a system meeting those requirements within the previous year.

d. Operating procedures.

(1) No individual other than the patient shall be in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system shall not be used in the administration of radiation therapy unless the requirements of subdivisions a, b, and c ~~of this subsection~~ have been met.

History: Amended effective October 1, 1982; June 1, 1986; June 1, 1992; March 1, 1994; May 1, 1998; March 1, 2003.
General Authority: NDCC 23-20.1-04
Law Implemented: NDCC 23-20.1-03, 23-20.1-04

33-10-06-12. Bone densitometry.

1. Bone densitometry systems shall be:

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

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

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

2. Equipment requirements. Systems with stepless collimators shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond two percent of the source-image receptor distance.

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

   a. Basic radiation protection;

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

   c. Patient positioning for the type of examinations performed.

4. During the operation of any bone densitometry system:

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

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

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

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

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

   b. Under a screening program approved by the department.

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

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