

CHAPTER 33.1-10-15 THERAPEUTIC RADIATION MACHINES

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33.1-10-15-01. Scope.

1. This chapter establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this chapter are in addition to, and not in substitution for, other applicable provisions of these regulations.
2. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established by subsection 3 of section 33.1-10-15-03.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

33.1-10-15-02. Definitions.

As used in this chapter, the following definitions apply:

1. "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.
2. "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.
3. "Accelerator-produced material" means any material made radioactive by exposing it in a particle accelerator.
4. "Accessible surface" means surface of equipment or of an equipment part that can be touched by persons without the use of a tool.
5. "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).
6. "Added filtration" means any filtration which is in addition to the inherent filtration.
7. "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM.

The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

8. "Barrier" (see "protective barrier").
9. "Beam axis" means the axis of rotation of the beam-limiting device from the source through the centers of the x-ray field.
10. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the useful beam.
11. "Beam-monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.
12. "Beam-scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.
13. "Bent-beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.
14. "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.
15. "Calibration" means the determination of:
 - a. The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
 - b. The strength of a source of radiation relative to a standard.
16. "CFR" means the Code of Federal Regulations.
17. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.
18. "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.
19. "Department" means the department of environmental quality.
20. "Detector" (see "radiation detector").
21. "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.
22. "Dose equivalent H_T " means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.
23. "Dose monitor unit (DMU)" means a unit response from the beam-monitoring system from which the absorbed dose can be calculated.
24. "Electron applicator" means any accessory device utilized during electron therapy which determines the extent of the treatment area at a given distance from the source.

25. "Entrance" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.
26. "Exposure" means being exposed to ionizing radiation or to radioactive material.
27. "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
28. "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.
29. "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
30. "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.
31. "Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to one joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. [1 Gy = 100 rad].
32. "Half-value layer (HVL)" means the thickness of a specified material which attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.
33. "Healing arts" means diagnostic or healing treatment of human and animal maladies, including the following which are duly licensed by the state of North Dakota for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.
34. "Individual" means any human being.
35. "Inspection" means an official examination or observation, including tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the department.
36. "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.
37. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
38. "Irradiation" means the exposure of a living being or matter to ionizing radiation.
39. "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.
40. "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: Current convention is to use kV for photons and keV for electrons.]
41. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
42. "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

- a. The useful beam; and
 - b. Radiation produced when the exposure switch or timer is not activated.
43. "Light field" means the area illuminated by light, simulating the radiation field.
44. "mA" means milliampere.
45. "Medical use" means the intentional internal or external administration of radiation or radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in chapter 33.1-10-07.2-01 [10 CFR 35.2].
46. "Megavolt (MV) [megaelectron volt (MeV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: Current convention is to use MV for photons and MeV for electrons.]
47. "Monitor unit (MU)" (see "dose monitor unit").
48. "Monitoring" means the measurement of radiation and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.
49. "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation, and rotational therapy.
50. "Nominal treatment distance" means:
- a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
 - b. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.
51. "Patient" means an individual or animal subjected to radiation for the purposes of diagnosis or treatment.
52. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
53. "Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.
54. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the commission, or any successor thereto and other than federal government agencies licensed by the commission or any successor thereto.
55. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to absorption and scattering of the ionizing radiation in question.
56. "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

57. "Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays. A further explanation may be found in "clinical electron beam dosimetry: report of AAPM radiation therapy committee task group 25" [Medical Physics 18(1): 73-109, Jan./Feb. 1991] and ICRU report 35, "radiation dosimetry: electron beams with energies between 1 and 50 MeV", international commission on radiation units and measurements, September 15, 1984.
58. "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.
59. "Primary protective barrier" (see "protective barrier").
60. "Protective barrier" means a barrier of radiation absorbing 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.
 - b. "Secondary protective barrier" means the material which attenuates stray radiation.
61. "Qualified expert" means an individual having the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American board of medical physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, "qualified expert" means an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in therapeutic radiological physics or x-ray and radium physics by the American board of radiology, or those having equivalent qualifications.
62. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of one hundred erg per gram or one one-hundredth joule per kilogram (0.01 gray).
63. "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.
64. "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
65. "Radiation exposure" means the quotient of dQ by dm where " dQ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " dm " are completely stopped in air. The SI unit of radiation exposure is the coulomb per kilogram (C/kg). (See section 33.1-10-01-14 units of exposure, dose, and activity for the special unit equivalent "roentgen" (R).)
66. "Radiation exposure rate" means the radiation exposure per unit of time, such as R/min, mR/h, etc.
67. "Radiation field" (see "useful beam").
68. "Radiation head" means the structure from which the useful beam emerges.

69. "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.
70. "Radiation therapy physicist" means an individual qualified in accordance with subsection 4 of section 33.1-10-15-03.
71. "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
72. "Redundant beam-monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.
73. "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to this article and North Dakota Century Code chapter 23.1-03.
74. "Registration" means the notification of the department of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with North Dakota Century Code chapter 23.1-02.
75. "Rem" (see "sievert").
76. "Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation or radioactive material. "Restricted area" does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.
77. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.
78. "Secondary dose-monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose-monitoring system.
79. "Secondary protective barrier" (see "protective barrier").
80. "Shadow tray" means a device attached to the radiation head to support auxiliary beam-blocking material.
81. "Shutter" means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
82. "Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert. [1 Sv = 100 rem].
83. "Source" means the region or material, or both, from which the radiation emanates.
84. "Source-skin distance (SSD)" (see "target-skin distance").
85. "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axis relative to the patient during irradiation.
86. "Stray radiation" means the sum of leakage and scattered radiation.

87. "Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.
88. "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source, or both, to the surface of the irradiated object or patient.
89. "Tenth-value layer (TVL)" means the thickness of a specified material which attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.
90. "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
91. "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof. "Test" may also mean the process of verifying compliance with this article.
92. "Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy.
93. "Tube" means an x-ray tube, unless otherwise specified.
94. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.
95. "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.
96. "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.
97. "Virtual source" means a point from which radiation appears to originate.
98. "Wedge filter" means an added filter effecting continuous progressive attenuation on all or a part of the useful beam.
99. "X-ray tube" means any electron tube which is designed for conversion of electrical energy into x-ray energy.

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33.1-10-15-03. General administration requirements.

1. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the department. The registrant or the registrant's agent shall ensure that the requirements of chapter 33.1-10-15 are met in the operation of the therapeutic radiation machines.
2. A therapeutic radiation machine that does not meet the provisions of these regulations shall not be used for irradiation of patients.

3. Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to section 33.1-10-15-06 or 33.1-10-15-07 shall require the authorized user to be a physician who:
 - a. Is certified in:
 - (1) Radiology or therapeutic radiology by the American board of radiology;
 - (2) Radiation oncology by the American osteopathic board of radiology;
 - (3) Radiology, with specialization in radiotherapy, as a British "fellow of the faculty of radiology" or "fellow of the royal college of radiology"; or
 - (4) Therapeutic radiology by the Canadian royal college of physicians and surgeons; or
 - b. Is in the active practice of therapeutic radiology, and has completed two hundred hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred hours of supervised work experience, and a minimum of three years of supervised clinical experience.
 - (1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of ionization radiation; and
 - (d) Radiation biology.
 - (2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:
 - (a) Review of the full calibration measurements and periodic quality assurance checks;
 - (b) Evaluation of prepared treatment plans and calculation of treatment times and patient treatment settings;
 - (c) Using administrative controls to prevent misadministrations;
 - (d) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
 - (e) Checking and using radiation survey meters.
 - (3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the residency review committee for radiology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American osteopathic association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

- (a) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations or contraindications;
 - (b) Selecting proper dose and how it is to be administered;
 - (c) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses or treatment plans, or both, as warranted by patients' reaction to radiation; and
 - (d) Postadministration followup and review of case histories.
 - c. Notwithstanding the requirements of subdivision a or b, the registrant for any therapeutic radiation machine subject to section 33.1-10-15-06 may also submit the training of the prospective authorized user physician for department review on a case-by-case basis.
 - d. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the facility and is determined to meet the requirements.
4. Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to section 33.1-10-15-06 or 33.1-10-15-07 shall require the radiation therapy physicist to:
- a. Be registered with the department, under the provisions of chapter 33.1-10-02, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and
 - b. Be certified or eligible for certification by the American board of radiology in:
 - (1) Therapeutic radiological physics;
 - (2) Roentgen-ray and gamma-ray physics;
 - (3) X-ray and radium physics; or
 - (4) Radiological physics;
 - c. Be certified or eligible for certification by the American board of medical physics in radiation oncology physics;
 - d. Be certified or eligible for certification by the Canadian college of medical physics; or
 - e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in subsection 2 of section 33.1-10-15-04, subsection 16 of section 33.1-10-15-06, subsection 20 of section 33.1-10-15-07, subsection 17 of section 33.1-10-15-06, and subsection 21 of section 33.1-10-15-07 under the supervision of a radiation therapy physicist during the year of work experience.
5. Qualifications of operators.
- a. Individuals who will be operating a therapeutic radiation machine for medical use shall be American registry of radiologic technologists (ARRT) registered radiation therapy technologists. Individuals who are not ARRT registered radiation therapy technologists

shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the joint review committee on education in radiologic technology.

- b. The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.
6. Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.
7. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who meets the requirements of subsection 3. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.
8. Visiting authorized user. Notwithstanding the provisions of subsection 7, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's certificate of registration for up to sixty days per calendar year under the following conditions:
 - a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;
 - b. The visiting authorized user meets the requirements established for authorized users in subdivisions a and b of subsection 3; and
 - c. The registrant maintains copies of all records specified by this subsection for five years from the date of the last visit.
9. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of this chapter, these individuals are also subject to the requirements of chapter 33.1-10-04.2-01 [10 CFR 20.1203 and 10 CFR 20.1502].
10. Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the department:
 - a. Report of acceptance testing;
 - b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this chapter, as well as the names of persons who performed such activities;
 - c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine on or after January 1, 2011, as well as the names of persons who performed such services; and
 - d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.
11. Records retention. All records required by this chapter shall be retained until disposal is authorized by the department unless another retention period is specifically authorized in this

chapter. All required records shall be retained in an active file from at least the time of generation until the next department inspection. Any required record generated prior to the last department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the department authorizes final disposal.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

33.1-10-15-04. General technical requirements.

1. Protection surveys.
 - a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with section 33.1-10-15-08. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a qualified expert and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:
 - (1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in chapter 33.1-10-04.2-01 [10 CFR 20.1201]; and
 - (2) Radiation levels in unrestricted areas do not exceed the limits specified in chapter 33.1-10-04.2-01 [10 CFR 20.1301].
 - b. In addition to the requirements of subdivision a, a radiation protection survey shall also be performed prior to any subsequent medical use and:
 - (1) After making any change in the treatment room shielding;
 - (2) After making any change in the location of the therapeutic radiation machine within the treatment room;
 - (3) After relocating the therapeutic radiation machine; or
 - (4) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.
 - c. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a qualified expert, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instruments used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey;
 - d. If the results of the surveys required by subdivision a or b indicate any radiation levels in excess of the respective limit specified in subdivision a, the registrant shall lock the control in the "OFF" position and not use the unit:

- (1) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or
 - (2) Until the registrant has received a specific exemption from the department.
2. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by subsection 1 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by chapter 33.1-10-04.2-01 [10 CFR 20.1301], before beginning the treatment program the registrant shall:
 - a. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with chapter 33.1-10-04.2-01 [10 CFR 20.1301];
 - b. Perform the survey required by subsection 1 again; and
 - c. Include in the report required by subsection 4 the results of the initial survey, a description of the modification made to comply with subdivision a, and the results of the second survey; or
 - d. Request and receive a registration amendment under chapter 33.1-10-04.2-01 [10 CFR 20.1301] that authorizes radiation levels in unrestricted areas greater than those permitted by chapter 33.1-10-04.2-01 [10 CFR 20.1301(a) and 10 CFR 20.1301(b)].
3. Dosimetry equipment.
 - a. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the national institute for standards and technology (NIST) or by an American association of physicists in medicine (AAPM) accredited dosimetry calibration laboratory (ADCL). The calibration shall have been performed within the previous twenty-four months and after any servicing that may have affected system calibration. An independent survey shall be conducted by a qualified expert or radiation therapy physicist other than the person performing the original survey prior to the equipment being used except as described in subdivision d of subsection 1.
 - (1) For beams with energies greater than one million volts (1 Mv) or one million electron volts (1 MeV), the dosimetry system shall have been calibrated for cobalt-60; or
 - (2) For beams with energies equal to or less than one million volts (1 Mv) or one million electron volts (1 MeV), the dosimetry system shall have been calibrated at an energy appropriate for the radiation being measured;
 - b. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subdivision a. This comparison shall have been performed within the previous twelve months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in subdivision a; and
 - c. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record shall include the date; the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subdivisions a and b; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

4. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to section 33.1-10-15-06 or 33.1-10-15-07 shall furnish a copy of the records required in subsections 1 and 2 to the department within thirty days following completion of the action that initiated the record requirement.

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33.1-10-15-05. Quality management program.

The facility shall implement a quality management program. The facility may use the quality management programs found in either appendix B or C.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

33.1-10-15-06. Therapeutic radiation machines of less than five hundred kilovolts.

1. Leakage radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kilovolts, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:
 - a. Five to fifty kilovolts systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one milligray (100 mrad) in any one hour.
 - b. Greater than fifty and less than five hundred kilovolts systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one centigray (1 rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed thirty centigray (30 rad) per hour.
 - c. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions a and b for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.
2. Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.
3. Adjustable or removable beam-limiting devices.
 - a. All adjustable or removable beam-limiting devices, diaphragms, cones, or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used; and
 - b. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.
4. Filter system. The filter system shall be so designed that:
 - a. Filters cannot be accidentally displaced at any possible tube orientation;
 - b. An interlock system prevents irradiation if the proper filter is not in place;

- c. The air kerma rate escaping from the filter slot shall not exceed one centigray (1 rad) per hour at one meter under any operating conditions; and
 - d. Each filter shall be marked as to its material of construction and its thickness. For wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray, if permanently mounted to the tray.
5. Tube immobilization.
 - a. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and
 - b. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.
6. Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
7. Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to five-tenths millimeters of lead at one hundred kilovolts, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.
8. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.
 - a. A timer with a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;
 - b. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;
 - c. The timer shall terminate irradiation when a preselected time has elapsed, if any dose-monitoring system present has not previously terminated irradiation;
 - d. The timer shall permit accurate presetting and determination of exposure times as short as one second;
 - e. The timer shall not permit an exposure if set at zero;
 - f. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
 - g. Timer shall be accurate to within one percent of the selected value or one second, whichever is greater.
9. Control panel functions. The control panel, in addition to the displays required by other provisions in this section, shall have:
 - a. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 - b. An indication of whether x-rays are being produced;

- c. A means for indicating x-ray tube potential and current;
 - d. The means for terminating an exposure at any time;
 - e. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
 - f. A positive display of specific filters in the beam.
10. Multiple tubes. When a control panel may energize more than one x-ray tube:
- a. It shall be possible to activate only one x-ray tube at any time;
 - b. There shall be an indication at the control panel identifying which x-ray tube is activated; and
 - c. There shall be an indication at the tube housing assembly when that tube is energized.
11. Target-to-skin distance (TSD). There shall be a means of determining the central axis target-to-skin distance to within one centimeter and of reproducing this measurement to within two millimeters thereafter.
12. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.
13. Low filtration x-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.
14. Facility design requirements for therapeutic radiation machines capable of operating in the range fifty kilovolts to five hundred kilovolts. In addition to shielding adequate to meet requirements of section 33.1-10-15-09, the treatment room shall meet the following design requirements:
- a. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.
 - b. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.
15. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above one hundred fifty kilovolts shall meet the following additional requirements:
- a. All protective barriers shall be fixed except for entrance doors or beam interceptors;
 - b. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
 - c. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine

to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

- d. When any door referred to in subdivision c is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one milligray (100 mrad) per hour.

16. Full calibration measurements.

- a. Full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a radiation therapy physicist:
 - (1) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
 - (2) At intervals not exceeding one year; and
 - (3) Before medical use under the following conditions:
 - (a) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
 - (b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
 - (4) Notwithstanding the requirements of paragraph 3:
 - (a) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes or energies, or both, that are not within their acceptable range; and
 - (b) If the repair, replacement, or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in subparagraph a of paragraph 3.
- b. To satisfy the requirement of subdivision a, full calibration shall include all measurements recommended for annual calibration by NCRP report 69, "dosimetry of x-ray and gamma ray beams for radiation therapy in the energy range ten keV to fifty MeV" (1981).
- c. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

17. Periodic quality assurance checks.

- a. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this section, which are capable of operation at greater than or equal to fifty kilovolts.
- b. To satisfy the requirement of subdivision a, quality assurance checks shall meet the following requirements:

- (1) The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and
 - (2) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subdivision a of subsection 16. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subdivision a of subsection 16, shall be stated.
- c. The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient irradiation.
 - d. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in subdivision a of subsection 16.
 - e. The registrant shall use the dosimetry system described in subdivision b of subsection 3 of section 33.1-10-15-04 to make the quality assurance check required in subdivision b.
 - f. The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed.
 - g. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to section 33.1-10-15-06 are performed at intervals not to exceed one month.
 - h. Notwithstanding the requirements of subdivisions f and g, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by subdivisions f and g have been performed within the thirty-day period immediately prior to said administration.
 - i. To satisfy the requirement of subdivision g, safety quality assurance checks shall ensure proper operation of:
 - (1) Electrical interlocks at each external beam radiation therapy room entrance;
 - (2) The "BEAM-ON" and termination switches;
 - (3) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
 - (4) Viewing systems; and
 - (5) If applicable, electrically operated treatment room doors from inside and outside the treatment room.
 - j. The registrant shall maintain a record of each quality assurance check required by subdivision g for three years. The record shall include the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number, and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

18. Operating procedures.
 - a. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subsection 16 of section 33.1-10-15-06 and subsection 17 of this section have been met;
 - b. Therapeutic radiation machines shall not be left unattended unless secured pursuant to subdivision e of subsection 9;
 - c. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;
 - d. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed fifty kilovolts. In such cases, the holder shall wear protective gloves and apron of not less than five-tenths millimeters lead equivalency at one hundred kilovolts;
 - e. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and
 - f. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above one hundred fifty kilovolts. At energies less than or equal to one hundred fifty kilovolts, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of chapter 33.1-10-04.2-01 [10 CFR 20.1201].
19. Possession of survey instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsievert (1 mrem) per hour to ten millisievert (1,000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with section 33.1-10-15-08.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

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33.1-10-15-07. Therapeutic radiation machines - Photon therapy systems (five hundred kilovolts and above) and electron therapy systems (five hundred kilo electron volts and above).

1. Possession of survey instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten microsieverts (1 mrem) per hour to ten millisieverts (1,000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with section 33.1-10-15-08.
2. Leakage radiation outside the maximum useful beam in photon and electron modes.
 - a. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of two-tenths percent and an average of one-tenth percent of the absorbed dose on the beam axis at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters at a minimum of sixteen points uniformly distributed in the plane;

- b. Except for the area defined in subdivision a, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed five-tenths percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters;
 - c. For equipment manufactured after January 1, 2011, the neutron absorbed dose outside the useful beam shall be in compliance with international electrotechnical commission (IEC) document 601-2-1 (most current revision); and
 - d. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in subdivisions a and c for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.
3. Leakage radiation through beam-limiting devices.
- a. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting devices shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field.
 - b. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:
 - (1) A maximum of two percent and average of five-tenths percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
 - (2) A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.
 - c. Measurement of leakage radiation.
 - (1) Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two tenth-value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters; and
 - (2) Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.
4. Filters and wedges.

- a. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;
 - b. If the absorbed dose rate information required by subsection 2 relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such foil or filter shall be removable only by the use of tools; and
 - c. For equipment which utilizes wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:
 - (1) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
 - (2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - (3) A display shall be provided at the treatment control panel showing the wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils, or both, in use; and
 - (4) An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation, or both, carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation, or both, carried out at the treatment control panel.
5. Stray radiation in the useful beam. For equipment manufactured after January 1, 2011, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation, in the useful electron beam, absorbed dose at the surface during x-ray irradiation, and stray neutron radiation in the useful x-ray beam are in compliance with international electrotechnical commission (IEC) document 601-2-1 (most current revision).
6. Beam monitors. All therapeutic radiation machines subject to this section shall be provided with redundant beam-monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.
- a. Equipment shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.
 - b. The detector and the system into which that detector is incorporated shall meet the following requirements:
 - (1) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
 - (2) Each detector shall form part of a beam-monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
 - (3) Each beam-monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and
 - (4) The design of the beam-monitoring systems shall ensure that the:

- (a) Malfunctioning of one system shall not affect the correct functioning of the other systems; and
 - (b) Failure of either system shall terminate irradiation or prevent the initiation of radiation; and
- (5) Each beam-monitoring system shall have a legible display at the treatment control panel. Each display shall:
 - (a) Maintain a reading until intentionally reset;
 - (b) Have only one scale and no electrical or mechanical scale multiplying factors;
 - (c) Utilize a design such that increasing dose is displayed by increasing numbers; and
 - (d) In the event of power failure, the beam-monitoring information required in subparagraph c displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty-minute period of time.
- 7. Beam symmetry.
 - a. Bent-beam linear accelerators subject to this section shall be provided with auxiliary devices to monitor beam symmetry;
 - b. The devices referenced in subdivision a shall be able to detect field asymmetry greater than five percent; and
 - c. The devices referenced in subdivision a shall be configured to terminate irradiation if the specifications in subdivision b cannot be maintained.
- 8. Selection and display of dose monitor units.
 - a. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;
 - b. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;
 - c. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and
 - d. After termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.
- 9. Air kerma rate or absorbed dose rate. A system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in subsection 6 may form part of this system. In addition:
 - a. The dose monitor unit rate shall be displayed at the treatment control panel;
 - b. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

- c. If the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four gray (400 rad); and
 - d. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum values specified in subdivisions b and c for the specified operating conditions. Records of these maximum values shall be maintained at the installation for inspection by the department.
10. Termination of irradiation by the beam-monitoring system or systems during stationary beam radiation therapy.
- a. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;
 - b. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen percent or forty dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and
 - c. An indicator on the control panel shall show which monitoring system has terminated irradiation.
 - d. For new equipment, a secondary dose monitoring system must be present. That system must be capable of terminating irradiation when not more than ten percent or twenty-five dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.
11. Termination of irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.
12. Interruption of irradiation. It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
13. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.
- a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;
 - b. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;
 - c. After termination of irradiation and before irradiation can be reinitiated, it shall be necessary to reset the preset time selector; and
 - d. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

14. Selection of radiation type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
 - a. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
 - b. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;
 - c. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;
 - d. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
 - e. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
 - f. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
15. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
 - a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
 - b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
 - c. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;
 - d. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location;
 - e. An interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than twenty percent or three megaelectron volts, whichever is smaller, from the selected nominal energy; and
 - f. For equipment manufactured after January 1, 2011, the selection of energy shall be in compliance with international electrotechnical commission (IEC) document 601-2-1 (most current revision).
16. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:
 - a. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
 - b. The mode of operation shall be displayed at the treatment control panel;

- c. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;
 - d. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
 - e. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement.
 - (1) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than twenty percent from the selected value;
 - (2) Where the angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent from the dose monitor unit value selected;
 - (3) An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;
 - (4) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy; and
 - (5) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;
 - f. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by subsection 10; and
 - g. An interlock system shall be provided to terminate irradiation if movement:
 - (1) Occurs during stationary beam radiation therapy; or
 - (2) Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.
17. Facility design requirements for therapeutic radiation machines operating above five hundred kilovolts. In addition to shielding adequate to meet requirements of section 33.1-10-15-09, the following design requirements are made:
- a. Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;
 - b. Control panel. In addition to other requirements specified in this chapter, the control panel shall also:
 - (1) Be located outside the treatment room;
 - (2) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
 - (3) Provide an indication of whether radiation is being produced; and
 - (4) Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

- c. Viewing systems. Windows, mirrors, closed-circuit television, or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;
 - d. Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;
 - e. Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";
 - f. Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;
 - g. Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with chapter 33.1-10-04.2 [10 CFR 20.1301a and 10 CFR 20.1301b] of these regulations, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;
 - h. Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power, including radiation and mechanical motion. This switch is in addition to the termination switch required by subsection 11. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;
 - i. Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and
 - j. Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten million volts prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.
18. Radiation therapy physicist support.
- a. The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of five hundred kilovolts and above. The radiation therapy physicist shall be responsible for:
 - (1) Full calibrations required by subsection 20 and protection surveys required by subsection 1 of section 33.1-10-15-04;
 - (2) Supervision and review of dosimetry;
 - (3) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

- (4) Quality assurance, including quality assurance check review required by subdivision e of subsection 21;
 - (5) Consultation with the authorized user in treatment planning, as needed; and
 - (6) Perform calculations and assessments regarding misadministrations.
- b. If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by subsection 17 shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.
19. Operating procedures.
- a. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;
 - b. Therapeutic radiation machines shall not be made available for medical use unless the requirements of subsection 1 of section 33.1-10-15-04 and subsections 20 and 21 of this section have been met;
 - c. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;
 - d. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;
 - e. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and
 - f. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
20. Acceptance testing, commissioning, and full calibration measurements.
- a. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a radiation therapy physicist.
 - b. Acceptance testing and commissioning shall be performed in accordance with "American association of physicists in medicine code of practice for radiotherapy accelerators: report of American association of physicists in medicine radiation therapy task group 45" and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.
 - c. Full calibration shall include measurement of all parameters required by table II of "comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40" and shall be performed in accordance with "American association of physicists in medicine code of practice for radiotherapy accelerators: report of American association of physicists in medicine radiation therapy task group 45". Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding twelve calendar months, unless a more frequent interval is required in table II.
 - d. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- (1) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy or multimode capabilities, or both, shall only require measurements for those modes or energies, or both, which are not within their acceptable range; and
 - (2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes or energies, measurements shall be performed on the affected mode or energy that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in paragraph 1.
- e. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.
21. Periodic quality assurance checks.
- a. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to this section at intervals not to exceed those specified in "comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40";
 - b. To satisfy the requirement of subdivision a, quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40". Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed twelve consecutive calendar months;
 - c. The registrant shall use a dosimetry system that has been intercompared within the previous twelve months with the dosimetry system described in subdivision a of subsection 3 of section 33.1-10-15-04 to make the periodic quality assurance checks required in subdivision b;
 - d. The registrant shall perform periodic quality assurance checks required by subdivision a in accordance with procedures established by the radiation therapy physicist;
 - e. The registrant shall review the results of each periodic radiation output check according to the following procedures:
 - (1) The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;
 - (2) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and
 - (3) The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month;

- f. Therapeutic radiation machines subject to this section shall have safety quality assurance checks listed in "comprehensive QA for radiation oncology: report of American association of physicists in medicine radiation therapy committee task group 40" performed at intervals not to exceed one week;
- g. To satisfy the requirement of subdivision e, safety quality assurance checks shall ensure proper operation of:
 - (1) Electrical interlocks at each external beam radiation therapy room entrance;
 - (2) Proper operation of the "BEAM-ON", interrupt, and termination switches;
 - (3) Beam condition indicator lights on the access doors, on the control console, and in the radiation therapy room;
 - (4) Viewing systems;
 - (5) Electrically operated treatment room doors from inside and outside the treatment room; and
 - (6) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;
- h. The registrant shall promptly repair any system identified in subdivision g that is not operating properly; and
- i. The registrant shall maintain a record of each quality assurance check required by subdivisions a and b for three years. The record shall include the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number, and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

33.1-10-15-08. Calibration of survey instruments.

- 1. The registrant shall ensure that the survey instruments used to show compliance with this chapter have been calibrated before first use, at intervals not to exceed twelve months, and following repair;
- 2. To satisfy the requirements of subsection 1, the registrant shall:
 - a. Calibrate all required scale readings up to ten millisieverts (1,000 mrem) per hour with an appropriate radiation source that is traceable to the national institute of standards and technology (NIST); and
 - b. Calibrate at least two points on each scale to be calibrated. These points should be at approximately one-third and two-thirds of full scale;
- 3. To satisfy the requirements of subsection 2, the registrant shall:

- a. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and
 - b. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty percent if a correction factor or graph is conspicuously attached to the instrument;
4. The registrant shall retain a record of each calibration required in subsection 1 for three years. The record shall include:
 - a. A description of the calibration procedure; and
 - b. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration; and
 5. The registrant may obtain the services of individuals registered by the department, or licensed by the United States nuclear regulatory commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required by subsection 4 shall be maintained by the registrant.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

33.1-10-15-09. Shielding and safety design requirements.

1. Each therapeutic radiation machine subject to section 33.1-10-15-06 or 33.1-10-15-07 shall be provided with such primary or secondary barriers, or both, as are necessary to ensure compliance with chapter 33.1-10-04.2 [10 CFR 20.1201 and 10 CFR 20.1301].
2. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in appendix A.

History: Effective January 1, 2019.

General Authority: NDCC 23.1-03-02; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

1. All therapeutic radiation machines.
 - a. Basic facility information, including name, telephone number, and department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number) of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structures.
 - b. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.
 - c. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.
2. Therapeutic radiation machines up to 150 Kv (photons only). In addition to the requirements listed in subsection 1, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kilovolts shall submit shielding plans which contain, as a minimum, the following additional information:
 - a. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;
 - b. Maximum design workload for the facility, including total weekly radiation output, (expressed in gray (rad) or air kerma at 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
 - c. A facility blueprint or drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north, normal location of the therapeutic radiation machine's radiation ports, the port's travel and traverse limits, general directions of the useful beam, locations of any windows and doors, and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with subsection 1 of section 33.1-10-04.2-06 [10 CFR 20.1201] of these regulations;
 - d. The structural composition and thickness or lead or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the rooms concerned;
 - e. The type of occupancy of all adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, showing distance to the closest areas where it is likely that individuals may be present; and
 - f. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry doors) and shielding material in the facility:
 - (1) If commercial software is used to generate shielding requirements, please also identify the software used and the version or revision date.
 - (2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

3. Therapeutic radiation machines over 150 kilovolts.

In addition to the requirements listed in subsection 1, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kilovolts or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

- a. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energies and types of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified;
- b. Maximum design workload for the facility, including total weekly radiation output (expressed in gray (rad) at 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
- c. Facility blueprint or drawing (including both floor plan and elevation view) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), types, thickness, and minimum density of shielding materials, direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls, and floor), as well as details of the doors and maze;
- d. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the rooms concerned;
- e. The type of occupancy of all adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, showing distance to the closest areas where it is likely that individuals may be present;
- f. Description of all assumptions that were in shielding calculations, including design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and uses of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor, and ceiling), and "allowed" radiation exposure in both restricted and unrestricted areas; and
- g. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary or leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors and maze) and shielding material in the facility:
 - (1) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date; and
 - (2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

4. Neutron shielding.

In addition to the requirements listed in subsection 3, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

- a. The structural composition, thickness, minimum density, and location of all neutron shielding material;

- b. Description of all assumptions that were used in neutron shielding calculations, including neutron spectra as a function of energy, neutron fluence rate, absorbed dose, and dose equivalent (due to neutrons) in both restricted and unrestricted areas;
 - c. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry doors and maze) and neutron shielding material utilized in the facility:
 - (1) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date; and
 - (2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.
 - d. The methods and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.
5. References.
- a. NCRP Report 147, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (2004).
 - b. NCRP Report 144, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (2003).
 - c. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

History: Effective January 1, 2019.

APPENDIX B

QUALITY MANAGEMENT PROGRAM

1. In addition to the definitions in section 33.1-10-15-02, the following definitions are applicable to this appendix B:
 - a. "Misadministration" means the administration of an external beam radiation therapy dose:
 - (1) Involving the wrong patient, wrong treatment modality, or wrong treatment site;
 - (2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;
 - (3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent; or
 - (4) When the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose.
 - b. "Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.
 - c. "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by fifteen percent or more from the weekly prescribed dose.
 - d. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site, and overall treatment period.
2. Scope and applicability. Each applicant or registrant subject to section 33.1-10-15-06 or 33.1-10-15-07 shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:
 - a. Prior to administration, a written directive is prepared for any external beam radiation therapy dose:
 - (1) Notwithstanding subdivision a, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;
 - (2) Notwithstanding subdivision a, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within forty-eight hours of the oral revision; and

- (3) Notwithstanding subdivision a, if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within twenty-four hours of the oral directive;
 - b. Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;
 - c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;
 - d. Each administration is in accordance with the written directive; and
 - e. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
3. Development of quality management program.
 - a. Each application for registration subject to section 33.1-10-15-06 or 33.1-10-15-07 shall include a quality management program, that specifies staff, duties, and responsibilities, and equipment and procedures as part of the application required by chapter 33.1-10-02. The registrant shall implement the program upon issuance of a certificate of registration by the department; and
 - b. Each existing registrant subject to section 33.1-10-15-06 or 33.1-10-15-07 shall, within thirty days of January 1, 2011, submit to the department a written certification that a quality management program has been implemented.
4. As a part of the quality management program, the registrant shall:
 - a. Develop procedures for, and conduct a review of, the quality management program, including since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;
 - b. Conduct these reviews at intervals not to exceed twelve months;
 - c. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of subsection 2; and
 - d. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three years.
5. The registrant shall evaluate and respond, within thirty days after discovery of the recordable event, to each recordable event by:
 - a. Assembling the relevant facts, including the cause;
 - b. Identifying what, if any, corrective action is required to prevent recurrence; and
 - c. Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.
6. The registrant shall retain:

- a. Each written directive; and
 - b. A record of each administered radiation dose, in an auditable form, for three years after the date of administration.
7. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.
8. The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:
- a. Notify the department by telephone no later than the next calendar day after discovery of the misadministration;
 - b. Submit a written report to the department within fifteen days after discovery of the misadministration. The written report shall include the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;
 - c. Notify the referring physician and also notify the patient of the misadministration no later than twenty-four hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within twenty-four hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;
 - d. Retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and
 - e. If the patient was notified, furnish, within fifteen days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the department, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the department can be obtained from the registrant.
9. Aside from the notification requirement, nothing in subsection 8 of section 33.1-10-15-05 affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

History: Effective January 1, 2019.

APPENDIX C

ALTERNATIVE QUALITY MANAGEMENT PROGRAM

1. In addition to the definitions in section 33.1-10-15-02, the following definitions are applicable to this appendix C:
 - a. "Misadministration" means the administration of an external beam radiation therapy dose:
 - (1) Involving the wrong patient, wrong treatment modality, or wrong treatment site;
 - (2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;
 - (3) When the calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent; or
 - (4) When the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose;
 - b. "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by fifteen percent or more from the weekly prescribed dose; and
 - c. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site, and overall treatment period.
2. Each registrant shall establish and maintain a written program to provide assurance that radiation is administered to humans as directed by the authorized user. The program shall include the following elements:
 - a. Procedure for preparing written directives for the administration of radiation; however, a written directive is not required when an authorized user personally administers a dosage provided the pertinent facts are documented as otherwise required;
 - b. Procedure for verifying by more than one method the identity of the individual to be administered radiation;
 - c. Procedure for updating the therapy operating and emergency procedures manual;
 - d. Procedure for verifying that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
 - e. Procedures assuring that administration of radiation is carried out as specified in the written directive or the therapy operating and emergency procedures manual; and
 - f. Procedures for identifying and evaluating unintended deviations from the written directive or the therapy operating and emergency procedures manual including taking appropriate action for recordable events and misadministrations.
3. Each registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:

- a. Notify the department by telephone no later than the next calendar day after discovery of the misadministration;
 - b. Submit a written report to the department within fifteen days after discovery of the misadministration. The written report shall include the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;
 - c. Notify the referring physician and also notify the patient of the misadministration no later than twenty-four hours after its discovery, unless the referring physician personally informs the registrant either that the physician will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within twenty-four hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary medical care as a result of the misadministrations, because of any delay in notification;
 - d. Retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the action taken to prevent recurrence; and
 - e. If the patient was notified, furnish, within fifteen days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the department, or a brief description or both the event and the consequences as they may affect the report submitted to the department can be obtained from the registrant.
4. Each registrant shall evaluate and respond to recordable events within thirty days after discovery by assembling the relevant facts, identifying the cause of the recordable event, and taking appropriate action, if any is required, to prevent recurrence.
 5. Each registrant shall conduct an annual evaluation of the human administration program, including any recommendations for changes to be made as well as any modifications made since the last evaluation and, if required, revise procedures to assure that the radiation is administered as directed by the authorized user. Modifications made to the program shall not decrease the effectiveness of the program.
 6. Each registrant shall retain, in auditable form, for three years:
 - a. Each written directive;
 - b. A record of each administered radiation dose where a written directive is required;
 - c. A record of each annual review of the program, including the evaluations and findings of the review; and
 - d. A record of each recordable event, the relevant facts, and any corrective actions taken.

History: Effective January 1, 2019.