

TITLE 180 CONTROL OF RADIATION

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180 NAC 20

TITLE 180 CONTROL OF RADIATION

CHAPTER 20 THERAPEUTIC RADIATION MACHINES FOR HUMAN USE

20-001 SCOPE AND AUTHORITY

20-001.01 180 NAC 20 provides special requirements for therapeutic radiation machines. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

20-001.02 The requirements of this 180 NAC 20 are in addition to, and not in substitution for applicable requirements in 180 NAC 1, 2, 3, 4, 6, 10, 15, 17 and 18.

20-002 DEFINITIONS: As used in 180 NAC 20, the following definitions apply:

Absorbed dose rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible surface means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

Added filtration means any filtration which is in addition to the inherent filtration.

Air kerma (K) means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE , where dE is the sum of the initial kinetic energies of all 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).

Barrier (See "Protective barrier").

Beam axis means the axis of rotation of the beam limiting device.

Beam-limiting device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimension of the useful beam.

Beam monitoring system means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

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.

Bent beam linear accelerator means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

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

Contact therapy system means a therapeutic machine with a short target to skin distance (TSD), usually less than 5 centimeters.

Conventional Simulator means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

Detector (See Radiation detector).

Dose monitor unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

Electronic brachytherapy means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

Electronic brachytherapy device means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

Electronic brachytherapy source means the x-ray tube component used in an electronic brachytherapy device.

External beam radiation therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening filter means a filter used to homogenize the absorbed dose rate over the radiation field.

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 180 NAC 20-006.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

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.

Intensity Modulated Radiation Therapy (IMRT) means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

Interlock means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Irradiation means the exposure of a living being or matter to ionizing radiation.

Isocenter means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

Kilovolt (kVp)[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.]

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

Leakage radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light field means that area illuminated by light, simulating the radiation field.

mA means milliampere.

Megavolt (MV) [mega electron volt (MeV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note current convention is to use MV for photons and MeV for electrons.]

Misadministration means an event that meets the criteria in 180 NAC 20-005.02.

Mobile Electronic Brachytherapy Service means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record

Monitor unit (MU) (See "Dose monitor unit").

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.

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 must be that specified by the manufacturer.

Patient means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Periodic quality assurance check means a procedure which is performed to ensure that a previous calibration continues to be valid.

Phantom means an object behaving in essentially the same manner as tissue, with respect to the absorption or scattering of the ionizing radiation in question.

Practical range of electrons means a 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.

Prescribed dose means the total dose and dose per fraction as documented in the written directive. The prescribed dose is a estimation from measured data from a specified therapeutic 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.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier see "Protective barrier".

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam.
- b. "Secondary protective barrier" means the material which attenuates stray radiation.

Radiation detector means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation field see "Useful beam".

Radiation head means the structure from which the useful beam emerges.

Radiological Medical Physicist means an individual qualified in accordance with 180 NAC 15-013.01.

Redundant beam monitoring system means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Scattered radiation means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

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

Secondary protective barrier see "Protective barrier".

Shadow tray means a device attached to the radiation head to support auxiliary beam blocking material.

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Simulator (radiation therapy simulation system) means any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. [See: Conventional Simulator and Virtual Simulator.]

Source means the region and/or material from which the radiation emanates.

Source-skin distance (SSD) see "Target-skin distance".

Stationary beam radiation therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray radiation means the sum of leakage and scattered radiation.

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.

Target-skin distance (TSD) means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

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.

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.

Therapeutic radiation machine means x-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these regulations, therapeutic radiation machine includes, but is not limited to devices used to administer used to administer electronic brachytherapy.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

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 therapeutic radiation machine to produce radiation.

Virtual Simulator means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

Virtual source means a point from which radiation appears to originate.

Wedge filter means a filter which effects continuous change in transmission over all or a part of the useful beam.

Written directive means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in 180 NAC 20-005.01.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

20-003 GENERAL ADMINISTRATIVE REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

20-003.01 Administrative Controls: The registrant will 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 will ensure that the requirements of 180 NAC 20 are met in the operation of the therapeutic radiation machine(s).

20-003.02 A therapeutic radiation machine that does not meet the provisions of these regulations can not be used for irradiation of patients.

20-003.03 Training for External Beam Radiation Therapy Users: The registrant of any therapeutic radiation machine subject to 180 NAC 20.006 or 20.007 must require the user to be a physician who is licensed in the State of Nebraska and who:

1. Is certified in:

- a. Radiology (combined diagnostic and therapeutic radiology program), therapeutic radiology or radiation oncology, by the American Board of Radiology; or
 - b. Radiation oncology by the American Osteopathic Board of Radiology; or
 - c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.
- a. To satisfy the requirement for instruction, the classroom and laboratory training must include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of ionization radiation; and
 - (4) Radiation biology.
 - b. To satisfy the requirement for supervised work experience, training must be under the supervision of an individual meeting the requirements of 180 NAC 20-003.03 and must include:
 - (1) Review of the full calibration measurements and periodic quality assurance checks;
 - (2) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
 - (3) Using administrative controls to prevent misadministrations;
 - (4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
 - (5) Checking and using radiation survey meters.
 - c. To satisfy the requirement for a period of supervised clinical experience, training must 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 individual meeting the requirements of 180 NAC 20-003.03. The supervised clinical experience must include:
 - (1) Examining individuals and reviewing their case histories to

- determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
- (2) Selecting proper dose and how it is to be administered;
 - (3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
 - (4) Post-administration follow-up and review of case histories.
- d. Notwithstanding the requirements of 180 NAC 20-003.03, item 1 and 2, the registrant for any therapeutic radiation machine subject to 180 NAC 20-006 may also submit the training of the prospective authorized user physician for Department review on a case-by-case basis.
- e. A physician must 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 Department.

20-003.04 Training for Radiological Medical Physicist: The registrant for any therapeutic radiation machine subject to 20 NAC 20-006 or 20-007 must require the individual to meet the training requirements of 180 NAC 15-013.01.

20-003.05 Qualifications of Operators:

1. Individuals who will be operating a therapeutic radiation machine for medical use must be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists must 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.^{1/}
2. The names and training of all personnel currently operating a therapeutic radiation machine must be kept on file at the facility. Information on former operators must be retained for a period of at least two (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

20-003.06 Written safety procedures and rules must be developed by a Radiological Medical Physicist and must 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 must be able to demonstrate familiarity with these rules.

^{1/} "Standards for Accredited Educational Program in Radiologic Sciences – Effective January 1, 2002", Joint Review Committee on Education in Radiologic Technology, January 1996; Revised 2001.

20-003.07 Individuals must 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. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

20-003.08 All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the registrant's quality management program. In addition to the requirements of 180 NAC 20, these individuals are also subject to the requirements of 180 NAC 4-005, 4-009 and 4-021.

20-003.09 Information and Maintenance Record and Associated Information: The registrant must maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Department:

1. Report of acceptance testing;
2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 180 NAC 20, as well as the name(s) of person(s) who performed such activities;
3. Records of maintenance and/or modifications performed on the therapeutic radiation machine, as well as the name(s) of person(s) who performed such services;
4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

20-003.10 Records Retention: All records required by 180 NAC 20 must be retained until disposal is authorized by the Department unless another retention period is specifically authorized in 180 NAC 20. All required records must be retained in an active file from the time of generation, until at least 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.

20-003.11 Visiting Authorized User: Notwithstanding the provisions of 180 NAC 20-003.07, 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 (60) days per calendar year under the following conditions:

1. 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 (where applicable); and
2. The visiting authorized user meets the requirements established for authorized user(s) in 180 NAC 20-003.03, item 1 and 2; and
3. The registrant must maintain copies of the written permission required in 180 NAC 20-003.11, item 1i and documentation that the visiting authorized user met the requirements of 180 NAC 20-003.03, item 2 for five (5) years from the date of the last visit.

20-004 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

20-004.01 Protection Surveys

20-004.01A The registrant must 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 180 NAC 20-008. The radiation protection survey must be performed by, or under the direction of, a Radiological Medical Physicist and must verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with and without 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 180 NAC 4-005.01; and
2. Radiation levels in unrestricted areas do not exceed the limits specified in Parts 180 NAC 4-013.01 and 180 NAC 4-013.02.

20-004.01B In addition to the requirements of 180 NAC 20-004.01A, a radiation protection survey must 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.

20-004.01C The survey record must indicate all instances where the facility, in the opinion of the Radiological Medical Physicist or a qualified expert, is in violation of applicable regulations. The survey record must also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

20-004.01D If the results of the surveys required by 180 NAC 20-004.01, A or B indicate any radiation levels in excess of the respective limit specified in 180 NAC 20-004.01A., the registrant must 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.

20-004.02 Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program If the survey required by 180 NAC 20-004.01 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 180 NAC 4-013.01 and 4-013.02, before beginning the treatment program the registrant must:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 180 NAC 4-013.01 and 4-013.02;
2. Perform the survey required by 180 NAC 20-004.01 again; and
3. Include in the report required by 180 NAC 20-004.04 the results of the initial survey, a description of the modification made to comply with 180 NAC 20-004.02A., and the results of the second survey; or
4. Request and receive a registration amendment under 180 NAC 4-013.04 that authorizes radiation levels in unrestricted areas greater than those permitted by 180 NAC 4-013.01 and 4-013.02.

20-004.03 Dosimetry Equipment

20-004.03A The registrant must have a calibrated dosimetry system available for use. The system must 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 must have been performed within the previous 24 months and after any servicing that may have affected system calibration. The dosimetry system must have been calibrated at an energy (energy range) appropriate for the radiation being measured.

20-004.03B The registrant must 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 180 NAC 20-004.03A. This comparison will have been performed within the previous 12 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 180 NAC 20-004.03A.

20-004.03C The registrant must 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 must include:

1. The date;
2. The model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 180 NAC 20-004.03A and B; the correction factors that were determined;
3. The names of the individuals who performed the calibration, intercomparison, or comparison; and

4. Evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Radiological Medical Physicist.

20-004.04 Reports of External Beam Radiation Therapy Surveys and Measurements: The registrant for any therapeutic radiation machine subject to 180 NAC 20-006 or 20-007 must furnish a copy of the records required in 180 NAC 20-004.01 and 20-004.02. to the Department within thirty (30) days following completion of the action that initiated the record requirement.

20-005 QUALITY MANAGEMENT PROGRAM: Each registrant or applicant subject to 180 NAC 20-006 or 20-007 must develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the user.

20-005.01 Scope and Applicability: The quality management program must address, as a minimum the following specific objectives:

1. Written Directives
 - a. A written directive must be dated and signed by a user prior to the administration of radiation. If because of the patient's condition, a delay in the 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 will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.
 - b. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and the number of fractions.
 - c. 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 the administration of the external beam dose, or the next fractional dose.
 - d. The registrant must retain a copy of the written directive for three years.
2. Procedures for Administration: The registrant must develop, implement, and maintain written procedures to provide high confidence that:
 - a. Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
 - b. Each administration is in accordance with the written directive;
 - c. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:
 - (1) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive;
 - (2) Verifying that any computer-generated calculations are correctly

transferred into the consoles of authorized therapeutic medical units;

- d. Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
- e. The registrant retains a copy of the procedures for administration for the duration of the registration.

20-005.02 Reports and Notifications of Misadministrations

20-005.03A A registrant must report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

20-005.02B Other than events that result from intervention by a patient or human research subject, a registrant must report any event in which the administration of an external beam radiation dose:

1. Involving the wrong patient, wrong treatment modality, or wrong treatment site; or
2. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30%; or
3. When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

20-005.02C The registrant must notify the Department by telephone not later than the next business day after the discovery of a misadministration.

20-005.02D The registrant must submit a written report to the Department within 30 days after the discovery of a misadministration. The written report must include:

1. The registrant's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. Actions, if any, that have been taken, or are planned to prevent recurrence;
7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

20-005.02E The report may not contain the individual's name or any other information that could lead to the identification of the individual.

20-005.02F The registrant must provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that s/he will inform the individual or that, based on medical

judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant must make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of 180 NAC 20-005.02E, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant must inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the registrant upon request. The registrant must provide such a written description if requested.

20-005.02G Aside from the notification requirement, nothing in this subsection affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relative or guardians.

20-005.02H The registrant must retain a record of misadministration in accordance with 180 NAC 20-005.03. A copy of the record required must be provided to the referring physician if other than the registrant within 15 days after discovery of the misadministration.

20-005.03 Records of Misadministrations: A registrant must retain a record of misadministration reported in accordance with 180 NAC 20-005.02 for three years. The record must contain the following:

1. The registrant's name and the names of the individuals involved ;
2. The identification number, if one has been assigned, of the individual who is the subject of the misadministration;
3. A brief description of the event; why it occurred; the effect, if any, on the individual;
4. The actions, if any, taken or planned to prevent recurrence; and
5. Whether the registrant notified the individual (or the individual's responsible relative or guardian), and, if not, whether such failure to notify was based on guidance from the referring physician.

20-006 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 kV.²

20-006.01 Leakage Radiation: When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate must not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

^{2/} "Standards for Accredited Educational Program in Radiologic Sciences – Effective January 1, 2002", Joint Review Committee on Education in Radiologic Technology, January 1996; Revised 2001.

1. 0-50 kV Systems The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly must not exceed 1 mGy (100 mrad) in any one hour.
2. >50 and <500 kV Systems The leakage air kerma rate measured at a distance of 1 meter from the target in any direction must not exceed 1 cGy (1 rad) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly must not exceed 30 cGy (30 rad) per hour.
3. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 180 NAC 20-006.01, items 1. and 2. for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.

20-006.02 Permanent Beam Limiting Devices: Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

20-006.03 Adjustable or Removable Beam Limiting Devices

1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks must not transmit more than 5% of the useful beam for the most penetrating beam used;
2. When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light beam.

20-006.04 Filter System: The filter system must be so designed that:

1. Filters can not be accidentally displaced at any possible tube orientation;
2. For equipment installed after July 11, 2009, an interlock system prevents irradiation if the proper filter is not in place;
3. The air kerma rate escaping from the filter slot does not exceed 1 cGy (1 rad) per hour at 1 meter under any operating conditions; and
4. Each filter is marked as to its material of construction and its thickness.

20-006.05 Tube Immobilization

1. The x-ray tube must be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and
2. The tube housing assembly must be capable of being immobilized for stationary portal treatments.

20-006.06 Source Marking: The tube housing assembly must be marked so that it is possible to determine the location of the source to within 5 millimeters, and such marking must be readily accessible for use during calibration procedures.

20-006.07 Beam Block: Contact therapy tube housing assemblies must have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

20-006.08 Timer: A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

1. A timer, with a display, must be provided at the treatment control panel. The timer must have a pre-set time selector and an elapsed time or time remaining indicator;
2. The timer must 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 will be necessary to reset the elapsed time indicator;
3. The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
4. The timer must permit accurate pre-setting and determination of exposure times as short as 1 second;
5. The timer must not permit an exposure if set at zero;
6. The timer must 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
7. The timer must be accurate to within 1% of the selected value or 1 second, whichever is greater.

20-006.09 Control Panel Functions: The control panel, in addition to the displays required by other provisions in 180 NAC 20-006, must have:

1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
2. An indication of whether x-rays are being produced;
3. A means for indicating x-ray tube potential and current;
4. The means for terminating an exposure at any time;
5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
6. For therapeutic radiation machines installed after July 11, 2009, a positive display of specific filter(s) in the beam.

20-006.10 Multiple Tubes: When a control panel may energize more than one x-ray tube:

1. It must be possible to activate only one x-ray tube at any time;
2. There must be an indication at the control panel identifying which x-ray tube is activated; and
3. There must be an indication at the tube housing assembly when that tube is energized.

20-006.11 Target-to-Skin Distance (TSD): There must be a means of determining the central axis TSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

20-006.12 Shutters: Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam must 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 must be controlled by the operator from the control panel. An indication of shutter position must appear at the control panel.

20-006.13 Low Filtration X-ray Tubes: Each therapeutic radiation machine equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must 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.

20-006.14 Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV: In addition to shielding adequate to meet requirements of 180 NAC 20-009, the treatment room must meet the following design requirements:

1. Aural Communication: Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel;
2. Viewing Systems: Provision must be made to permit continuous observation of the patient during irradiation and the viewing system must be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.

20-006.15 Additional Requirements: Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV must meet the following additional requirements:

1. All protective barriers must be fixed except for entrance doors or beam interceptors;
2. The control panel must be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks must be provided such that all entrance doors, including doors to any interior booths, must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
4. When any door referred to in 180 NAC 20-006.15, item 3. is opened while the X-ray tube is activated, the air kerma rate at a distance of 1 meter from the source must be reduced to less than 1 mGy (100 mrad) per hour.

20-006.16 Full Calibration Measurements

20-006.16A Full calibration of a therapeutic radiation machine subject to 180 NAC 20-006 must be performed by, or under the direct supervision of, a Radiological Medical 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 5% 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 180 NAC 20-006.16A.3:
 - a. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - b. If the repair, replacement or modification does not affect all energies, full calibration must 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 180 NAC 20-006.16A.3.a.

20-006.16B To satisfy the requirement of 180 NAC 20-006.16A, full calibration must 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 10 keV to 50 MeV" (1981).

20-006.16C The registrant must maintain a record of each calibration for the duration of the registration. The record must include:

1. The date of the calibration;
2. The manufacturer's name,
3. Model number, and serial number for the therapeutic radiation machine if applicable;
4. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
5. The signature of the Radiological Medical Physicist responsible for performing the calibration.

20-006.17 Periodic Quality Assurance Checks

20-006.17A Periodic quality assurance checks must be performed on therapeutic radiation machines subject to 180 NAC 20-006, which are capable of operation at greater than or equal to 50 kV.

20-006.17B To satisfy the requirement of 180 NAC 20-006.17A, quality assurance checks must meet the following requirements:

1. The registrant must perform quality assurance checks in accordance with written procedures established by the Radiological Medical Physicist.; and
2. The quality assurance check procedures must specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures must specify that the quality assurance check will be performed during the calibration specified in 180 NAC 20-006.16A. 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 180 NAC 20-006.16A, must be stated.

20-006.17C The cause for a parameter exceeding a tolerance set by the Radiological Medical Physicist must be investigated and corrected before the system is used for patient irradiation.

20-006.17D Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiological Medical Physicist's quality assurance check procedures, the system must be recalibrated as required in 180 NAC 20-006.16A.

20-006.17E The registrant must use the dosimetry system described in 180 NAC 20-004.03B, to make the quality assurance check required in 180 NAC 20-006.17B.

20-006.17F The registrant must have the Radiological Medical Physicist review and sign the results of each radiation output quality assurance check within 1 month of the date that the check was performed.

20-006.17G The registrant must ensure that quality assurance checks of therapeutic radiation machines subject to 180 NAC 20-006 are performed at intervals not to exceed 1 month.

20-006.17H Notwithstanding the requirements of 180 NAC 20-006.17F and G, the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 180 NAC 20-006.17F and G have been performed within the 30 day period immediately prior to said administration.

20-006.17I To satisfy the requirement of 180 NAC 20-006.17B, safety quality assurance checks must ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room

- entrance;
2. The "BEAM-ON" and termination switches;
 3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
 4. Viewing systems; and
 5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

20-006.17J The registrant must maintain a record of each quality assurance check required by 180 NAC 20-006.17A and G for three years. The record must include:

1. The date of the quality assurance check;
2. The manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name;
3. The manufacture's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
4. The signature of the individual who performed the periodic quality assurance check.

20-006.18 Operating Procedures

20-006.18A The therapeutic radiation machine must not be used for irradiation of patients unless the requirements of 180 NAC 20-006.16 and 20-006.17. have been met.

20-006.18B Therapeutic radiation machines must not be left unattended unless secured pursuant to 180 NAC 20-006.09 item 5.

20-006.18C When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used.

20-006.18D The tube housing assembly must 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 50 kV. In such cases, the holder must wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV.

20-006.18E A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

20-006.18F No individual other than the patient must be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room must be protected by a barrier sufficient to meet the requirements of 180 NAC 4-005.

20-006.18G Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 180 NAC 20-005 must possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 mSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) must be operable and calibrated in accordance with 180 NAC 20-008.

20-007 THERAPEUTIC RADIATION MACHINES – PHOTON THERAPY SYSTEMS (500 kV AND ABOVE) AND ELECTRON THERAPY SYSTEMS (500 keV and ABOVE)

20-007.01 Leakage Radiation Outside the Maximum Useful Beam In Photon and Electron Modes

20-007.01A 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 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), must not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

20-007.01B Except for the area defined in 180 NAC 20-007.01A, the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window must not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters.

20-007.01C For equipment manufactured after the effective date of these regulations, the neutron absorbed dose outside the useful beam must be in compliance with International Electrotechnical Commission (IEC) Documents 60601-2-1, 2007-3 Third Edition.

20-007.01D For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 180 NAC 20-007.01A through C for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.

20-007.02 Leakage Radiation Through Beam Limiting Devices

20-007.02A Photon Radiation: All adjustable or interchangeable beam limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) must not exceed 2% of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm² radiation field, or maximum available field

size if less than 100 cm² ;

20-007.02B Electron Radiation: All adjustable or interchangeable electron applicators must attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance must not exceed:

1. A maximum of 2% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line 7 centimeters outside the periphery of the useful beam; and
2. A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line 2 centimeters outside the periphery of the useful beam.

20-007.03 Measurement of Leakage Radiation

20-007.03A Photon Radiation: Measurements of leakage radiation through the beam limiting devices must 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 must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector of area not exceeding 10 square centimeters;

20-007.03B Electron Radiation: Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements must be made using 1 centimeter of water equivalent build up material.

20-007.04 Filters/Wedges

20-007.04A Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must 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 must be redetermined;

20-007.04B If the absorbed dose rate information required by 180 NAC 20-007.01 relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter must be removable only by the use of tools;

20-007.04C For equipment installed after July 11, 2009 which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

1. Irradiation must 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 must be provided to prevent irradiation if the filter selected is not in the correct position;
3. A display must be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and
4. An interlock must be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

20-007.05 Stray Radiation in the Useful Beam: For equipment installed after the effective date of these regulations, the registrant must 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 60601-2-1, 2007-3, 3rd edition.

20-007.06 Beam Monitors: All therapeutic radiation machines subject to 180 NAC 20-007 must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

20-007.06A Equipment installed after July 11, 2009 must 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.

20-007.06B Equipment installed on or before July 11, 2009 must be provided with at least one radiation detector. This detector must be incorporated into a useful beam monitoring system;

20-007.06C The detector and the system into which that detector is incorporated must meet the following requirements:

1. Each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;
2. Each detector must 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 must be capable of independently monitoring, interrupting, and terminating irradiation; and
4. For equipment installed after July 11, 2009, the design of the beam monitoring systems must ensure that the:
 - a. Malfunctioning of one system must not affect the correct functioning of the other system(s); and

- b. Failure of either system must terminate irradiation or prevent the initiation of radiation.
5. Each beam monitoring system must have a legible display at the treatment control panel. For equipment installed after July 11, 2009, each display must:
 - 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 180 NAC 20-007.06C5.c. displayed at the control panel at the time of failure must be retrievable in at least one system for a 20 minute period of time.

20-007.07 Beam Symmetry

20-007.07A Bent-beam linear accelerators with beam flattening filter(s) subject to 180 NAC 20-007 must be provided with auxiliary device(s) to monitor beam symmetry;

20-007.07B The device(s) referenced in 180 NAC 20-007.07A must be able to detect field asymmetry greater than 10%; and

20-007.07C The device(s) referenced in 180 NAC 20-007.07A must be configured to terminate irradiation if the specifications in 180 NAC 20-007.07B can not be maintained.

20-007.08 Selection and Display of Dose Monitor Units

20-007.08A Irradiation must not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel,

20-007.08B The pre-selected number of dose monitor units will be displayed at the treatment control panel until reset manually for the next irradiation,

20-007.08C After termination of irradiation, it will be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

20-007.08D For equipment installed after July 11, 2009 after termination of irradiation, it will be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

20-007.09 Air Kerma Rate/Absorbed Dose Rate: For equipment installed after July 11, 2009, a system must 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 180 NAC 20-007.06 may form part of this system. In addition:

1. The dose monitor unit rate must be displayed at the treatment control panel;
2. 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 must 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 must be a record maintained by the registrant;
3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device must 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 4 Gy (400 rad); and
4. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum value(s) specified in 180 NAC 20-007.09, item 2 and 3, for the specified operating conditions. Records of these maximum value(s) must be maintained at the installation for inspection by the Department.

20-007.10 Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy

20-007.10A Each primary system must terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

20-007.10B If the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

20-007.10C For equipment installed after July 11, 2009, an indicator on the control panel must show which monitoring system has terminated irradiation.

20-007.11 Termination of Irradiation: It must 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.

20-007.12 Interruption of Irradiation: If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements must be automatically terminated.

20-007.13 Timer: A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

1. A timer must be provided which has a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator.
2. The timer must 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 will be necessary to reset the elapsed time indicator.
3. The timer must terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

20-007.14 Selection of Radiation Type: Equipment capable of both x-ray therapy and electron therapy must meet the following additional requirements:

1. Irradiation must not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
2. The radiation type selected must be displayed at the treatment control panel before and during irradiation;
3. An interlock system must be provided to ensure that the equipment can principally emit only the radiation type that has been selected;
4. An interlock system must be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
5. An interlock system must be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
6. An interlock system must 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.

20-007.15 Selection of Energy: Equipment capable of generating radiation beams of different energies must meet the following requirements:

1. Irradiation will not be possible until a selection of energy has been made at the treatment control panel;
2. The nominal energy value selected must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it will be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and
3. Irradiation will not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.
4. For equipment manufactured after the effective date of these regulations, the selection of energy must be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1, 2007-3, third edition.

20-007.16 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 must meet the following requirements:

1. Irradiation will not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
2. The mode of operation must be displayed at the treatment control panel;
3. An interlock system must be provided to ensure that the equipment can operate only in the mode that has been selected;
4. An interlock system must 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;
5. Moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment installed after July 11, 2009:
 - a. An interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20% from the selected value;
 - b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than 5% from the dose monitor unit value selected;
 - c. An interlock must be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy;
 - d. An interlock must be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.
 - e. Moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.
6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by 180 NAC 20-007.10; and
7. For equipment installed after July 11, 2009, an interlock system must be provided to terminate irradiation if movement:
 - a. Occurs during stationary beam radiation therapy; or
 - b. Does not start or stop during moving beam radiation therapy unless such stoppage is a pre-planned function.

20-007.17 Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV: In addition to shielding adequate to meet requirements of 180 NAC 20-009, the following design requirements include:

1. Protective Barriers: All protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors;
2. Control Panel: In addition to other requirements specified in 180 NAC 20, the control panel must also:
 - a. Be located outside the treatment room;
 - b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
 - c. Provide an indication of whether radiation is being produced; and
 - d. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.
3. Viewing Systems: Windows, mirrors, closed-circuit television or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational;
4. Aural Communications: Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine must not be used for irradiation of patients unless continuous two-way aural communication is possible;
5. Room Entrances: Treatment room entrances must 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";
6. Entrance Interlocks: Interlocks must 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 must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;
7. Beam Interceptor Interlocks: If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 180 NAC 4-013.01 and 4-013.02, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);
8. Emergency Cutoff Switches: At least one emergency power cutoff switch must be located in the radiation therapy room and must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 180 NAC 20-007.11. All emergency power cutoff switches must 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.

9. Safety Interlocks: All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and
10. Surveys for Residual Radiation: Surveys for residual activity must be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

20-007.18 Radiological Medical Physicist Support

20-007.18A The services of a Radiological Medical Physicist is required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiological Medical Physicist must be responsible for:

1. Full calibration(s) required by 180 NAC 20-007.20 and protection surveys required by 180 NAC 20-004.01.;
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 180 NAC 20-007.21E.;
5. Consultation with the user in treatment planning, as needed; and
6. Perform calculations/assessments regarding misadministrations.

20-007.18B If the Radiological Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 180 NAC 20-007.19F must also specifically address how the Radiological Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Radiological Medical Physicist can be contacted.

20-007.19 Operating Procedures

20-007.19A No individual, other than the patient, must be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

20-007.19B Therapeutic radiation machines must not be made available for medical use unless the requirements of 180 NAC 20-004.01, 20-007.20 and 20-007.21 have been met;

20-007.19C Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized use;

20-007.19D When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

20-007.19E If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used; and

20-007.19F A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

20-007.20 Acceptance Testing, Commissioning and Full Calibration Measurements

20-007.20A Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 180 NAC 20-007 must be performed by, or under the supervision of, a Radiological Medical Physicist.

20-007.20B Acceptance testing and commissioning must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" and manufactures specifications and must be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

20-007.20C Full calibration must include measurement of all applicable parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46," prepared by Committee Task Group 40 and must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" prepared by Radiation Therapy Task Group 45. Although it must not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) must be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in Table II.

20-007.20D The Radiological Medical Physicist must 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 5% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities must require measurements for only those modes and/or energies that are not within their acceptable range; and
2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements must be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 180 NAC 20-007.20D.1.

20-007.20E The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number and serial number for the therapeutic radiation machine;
3. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
4. The signature of the Radiological Medical Physicist responsible for performing the calibration.

20-007.21 Periodic Quality Assurance Checks

20-007.21A Periodic quality assurance checks must be performed on all therapeutic radiation machines subject to 180 NAC 20-007 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46," Report of AAPM Radiation Therapy Committee Task Group 40; or other procedure.

20-007.21B To satisfy the requirement of 180 NAC 20-007.21A, quality assurance checks must 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 AAPM Radiation Therapy Committee Task Group 40". Representative sampling must include all applicable referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

20-007.21C The registrant must use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry systems described in 180 NAC 20-004.03A to make the periodic quality assurance checks required in 180 NAC 20-007.21B;

20-007.21D The registrant must perform periodic quality assurance checks required by 180 NAC 20-007.21A in accordance with written procedures established by the Radiological Medical Physicist;

20-007.21E The registrant must review the results of each periodic radiation output check according to the following procedures:

1. The user and Radiological Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be made available for subsequent medical use until the Radiological Medical 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 must be reviewed and signed by either the authorized user or Radiological Medical Physicist within 3 treatment days; and
3. The Radiological Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

20-007.21F Therapeutic radiation machines subject to 180 NAC 20-007 must have applicable safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46" prepared by AAPM Radiation Therapy Committee Task Group 40" performed at intervals not to exceed 1 week;

20-007.21G To satisfy the requirement of 180 NAC 20-007.21F, safety quality assurance checks must ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. Proper operation of the "BEAM-ON", interrupt and termination switches;
3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
4. Viewing systems;
5. Electrically operated treatment room door(s) from inside and outside the treatment room.

20-007.21H The registrant must promptly repair any system identified in 180 NAC 20-007.21G. that is not operating properly; and

20-007.21I The registrant must maintain a record of each quality assurance check required by 180 NAC 20-007.021A and G for 3 years. The record must include:

1. The date of the quality assurance check;
2. The manufacturer's name, model number, and serial number of the therapeutic radiation machine;
3. The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
4. The signature of the individual who performed the periodic quality assurance check.

20-007.21J Quality Assurance Checks for IMRT must:

1. Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;^{3/} and
2. Be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82"; and
3. Be performed in accordance with the manufacturer's contractual specifications.

20-008 CALIBRATION OF SURVEY INSTRUMENTS

20-008.01 The registrant must ensure that the survey instruments used to show compliance with 180 NAC 20 have been calibrated before first use, at intervals not to

³ IMRT is a rapidly evolving modality and the QA program must also evolve to handle new issues that arise

exceed 12 months, and following repair.

20-008.02 To satisfy the requirements of 180 NAC 20-008.01, the registrant must:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);
2. Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

20-008.03 To satisfy the requirements of 180 NAC 20-008.02, the registrant must:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and
2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

20-008.04 The registrant must retain a record of each calibration required in 180 NAC 20-008.01 for three years. The record must include:

1. A description of the calibration procedure; and
2. 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.

20-008.05 The registrant may obtain the services of individuals licensed by the Department, the U. S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations that contain information required by 180 NAC 20-008.04 must be maintained by the registrant.

20-009 SHIELDING AND SAFETY DESIGN REQUIREMENTS

20-009.01 Each therapeutic radiation machine subject to 180 NAC 20-006 or 20-007 must be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 180 NAC 4-005 and 4-013.

20-009.02 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 must 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 20-A.

20-010 QUALITY ASSURANCE FOR RADIATION THERAPY SIMULATION SYSTEMS

20-010.01 Quality assurance for a conventional or virtual simulator must include acceptance testing and periodic verification of system performance; and

20-010.02 Be performed in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No.40: AAPM Report No. 46" for a conventional simulator; or

20-010.03 Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83" for a virtual simulator.

20-011 ELECTRONIC BRACHYTHERAPY

20-011.01 Applicability: Electronic brachytherapy devices must be subject to the requirements of 180 NAC 20-011, and must be exempt for the requirements of 180 NAC 20-006.

20-011.01A An electronic brachytherapy device that does not meet the requirements of 180 NAC 20-11 must not be used for irradiation of patients; and

20-011.01B An electronic brachytherapy device must only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

20-011.02 Possession of Survey Instrument(s) Each facility location authorized to use an electronic brachytherapy device in accordance with 180 NAC 20-11 must possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) must be operable and calibrated in accordance with 180 NAC 20-008 for the applicable electronic brachytherapy source energy.

20-011.03 Facility Design Requirements for Electronic Brachytherapy Devices: In addition to shielding adequate to meet requirements of 180 NAC 20-009, the treatment room must meet the following design requirements:

20-011.03A If applicable, provision must be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

20-011.03B Access to the treatment room must be controlled by a door at each entrance.

20-011.03C Each treatment room must have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device must not be used for patient irradiation unless the patient can be observed.

20-011.03D For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room must be available, either as a portable shield and/or as localized shielded material around the treatment site.

20-011.03E For electronic brachytherapy devices capable of operating at greater than 150 kV: ^{4/}

1. The control panel must be located outside the treatment room; and
2. Electrical interlocks must be provided for all door(s) to the treatment room that will:
 - a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - b. Cause the source to be shielded when an entrance door is opened; and
 - c. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

20-011.04 Electrical Safety for Electronic Brachytherapy Devices

20-011.04A The high voltage transformer must be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

20-011.04B The high voltage transformer must be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

20-011.04C The high voltage transformer must have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

20-011.04D Equipment manufactured after the effective date of these regulations must be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

1. IEC 60601-1:
2. IEC 60601-1-2:2001;
3. IEC 60601-2-8; and
4. IEC 60601-2-17:

20-011.05 Control Panel Functions: The control panel, in addition to the displays required by other provisions in 180 NAC 20-011 must:

⁴ IMRT is a rapidly evolving modality and the QA program must also evolve to handle new issues that arise

20-011.05A Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

20-011.05B Provide an indication of whether x-rays are being produced;

20-011.05C Provide a means for indicating electronic brachytherapy source potential and current;

1. Provide the means for terminating an exposure at any time; and
2. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

20-011.06 Timer: A suitable irradiation control device (timer) must be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

20-011.06A A timer must be provided at the treatment control panel. The timer must indicate planned setting and the time elapsed or remaining;

20-011.06B The timer must not permit an exposure if set at zero;

20-011.06C The timer must be a cumulative device 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 must be necessary to reset the elapsed time indicator;

20-011.06D The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

20-011.06E The timer must permit setting of exposure times as short as 0.1 second; and

20-011.06F The timer must be accurate to within one (1) percent of the selected value or 0.1 second, whichever is greater.

20-011.07 Qualified Medical Physicist Support

20-011.07A The services of a Qualified Medical Physicist must be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist must be responsible for:

1. Evaluation of the output from the electronic brachytherapy source;
2. Generation of the necessary dosimetric information;
3. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
4. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in 20-011.11;

5. Consultation with the authorized user in treatment planning, as needed; and
6. Performing calculations/assessments regarding patient treatments that may constitute a misadministration.

20-011.07B If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 20-011.08 must also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

20-011.08 Operating Procedures

20-011.08A Only individuals approved by the authorized user, Radiation Safety Officer, or Qualified Medical Physicist must be present in the treatment room during treatment;

20-011.08B Electronic brachytherapy devices must not be made available for medical use unless the requirements of 180 NAC 20-004.01, 20-011.09 and 20-011.10 have been met;

20-011.08C The electronic brachytherapy device must be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

20-011.08D During operation, the electronic brachytherapy device operator must monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;

20-011.08E If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used;

20-011.08F Written procedures must be developed, implemented, and maintained for responding to an abnormal situation. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
2. The names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

20-011.08G A copy of the current operating and emergency procedures must be physically located at the electronic brachytherapy device control console⁵;

⁵ If the control console is integral to the electronic brachytherapy device, the required procedures must be kept where the operator is located during electronic brachytherapy device operation.

20-011.08H Instructions must be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and

20-011.08I The Radiation Safety Officer, or his/her designee, and an authorized user must be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist must inform the manufacturer of the event.

20-011.09 Safety Precautions for Electronic Brachytherapy Devices

20-11.09A A Qualified Medical Physicist must determine which persons in the treatment room require monitoring when the beam is energized;

20-011.09B An authorized user and a Qualified Medical Physicist must be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

20-011.09C A Qualified Medical Physicist and either an authorized user or a physician or electronic brachytherapy device operator, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, must be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

20-011.09D When shielding is required by 180 NAC 20-011.03D, the electronic brachytherapy device operator must use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist must designate shield locations sufficient to meet the requirements of 180 NAC 4-005 for any individual, other than the patient, in the treatment room; and

20-011.09E All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist must approve any deviation from this requirement and must designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

20-011.10 Electronic Brachytherapy Source Calibration Measurements

20-011.10A Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to 180 NAC 20-011 must be performed by, or under the direct supervision of, a Qualified Medical Physicist;

20-011.10B Calibration of the electronic brachytherapy source output must be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

20-011.10C Calibration of the electronic brachytherapy source output must utilize a dosimetry system described in 180 NAC 20-011.04C;

20-011.10D Calibration of the electronic brachytherapy source output must include, as applicable, determination of:

1. The output within two percent (2 %) of the expected value, if applicable, or determination of the output if there is no expected value;
2. Timer accuracy and linearity over the typical range of use;
3. Proper operation of back-up exposure control devices;
4. Evaluation that the relative dose distribution about the source is within five percent (5 %) of that expected; and
5. Source positioning accuracy to within one (1) millimeter within the applicator;

20-011.10E Calibration of the x-ray source output required by 180 NAC 20-011.10A through F must be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, the manufacturer's calibration protocol.

20-011.10F The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for it's electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

2-011.10G Quality assurance checks required by 20-011.11A through F must be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, or the manufacturer's quality assurance check protocol.

20-011.11 Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

20-011.11A Quality assurance checks must be performed on each electronic brachytherapy device subject to 180 NAC 20-011:

1. At the beginning of each day of use;
2. Each time the device is moved to a new room or site⁶; and
3. After each x-ray tube installation.

⁶ *Site* is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer. See 180 NAC 20-011.14 for additional clarification.

20-011.11B The registrant must perform periodic quality assurance checks required by 180 NAC 20-011.11A in accordance with procedures established by the Qualified Medical Physicist;

20-011.11C To satisfy the requirements of 180 NAC 20-011.11A, radiation output quality assurance checks must include as a minimum:

1. Verification that output of the electronic brachytherapy source falls within three percent (3 %) of expected values, as appropriate for the device, as determined by:
 - a. Output as a function of time, or
 - b. Output as a function of setting on a monitor chamber.
2. Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by 180 NAC 20-011.10; and
3. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm; and

20-011.11D The registrant must use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in 180 NAC 20-004.03A to make the quality assurance checks required in 180 NAC 20-011.03;

20-011.11E The registrant must review the results of each radiation output quality assurance check according to the following procedures:

1. An authorized user and Qualified Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device must not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
2. If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or Qualified Medical Physicist within two (2) days; and
3. The Qualified Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

20-011.11F To satisfy the requirements of 180 NAC 20-011.11A, safety device quality assurance checks must, at a minimum, assure:

1. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
2. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

3. Proper operation of radiation monitors, if applicable;
4. The integrity of all cables, catheters or parts of the device that carry high voltages; and
5. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
6. If the results of the safety device quality assurance checks required in 180 NAC 20-011.11F, indicate the malfunction of any system, a registrant must secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
7. The registrant must maintain a record of each quality assurance check required by 180 NAC 20-011.11C and G in an auditable form for three (3) years.
 - a. The record must include:
 - (1) The date of the quality assurance check;
 - (2) The manufacturer's name, model number and serial number for the electronic brachytherapy device;
 - (3) The name and signature of the individual who performed the periodic quality assurance check and the name and
 - (4) Signature of the Qualified Medical Physicist who reviewed the quality assurance check;
 - b. For radiation output quality assurance checks required by 180 NAC 20-011.11, item 3, the record must also include:
 - (1) The unique identifier for the electronic brachytherapy source and the manufacturer's name;
 - (2) Model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

20-011.12 Therapy-Related Computer Systems: The registrant must perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol must be followed.

20-011.12A Acceptance testing must be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing must include, as applicable, verification of:

- 1 The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;
3. The accuracy of isodose plots and graphic displays;
4. The accuracy of the software used to determine radiation source positions from radiographic images; and
5. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

20-011.12B The position indicators in the applicator must be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

20-011.12C Prior to each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the authorized user and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

20-011.13 Training

20-011.13A A registrant must provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in 180 NAC 20-011.08. If the interval between patients exceeds one year, retraining of the individuals must be provided.

20-011.13B In addition to the requirements of 180 NAC 20-003.03 for therapeutic radiation machine authorized users and 180 NAC 20-003.04 for Qualified Medical Physicists, these individuals must also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training must be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol must be followed. The training must include, but not be limited to:

1. Device-specific radiation safety requirements;
2. Device operation;
3. Clinical use for the types of use approved by the FDA;
4. Emergency procedures, including an emergency drill; and
5. The registrant's Quality Assurance Program.

20-011.13C A registrant must retain a record of individuals receiving instruction required by 180 NAC 20-011.13A and B for three (3) years. The record must include:

1. A list of the topics covered,
2. The date of the instruction,

3. The name(s) of the attendee(s), and
4. The name(s) of the individual(s) who provided the instruction.

20-011.14 Mobile Electronic Brachytherapy Service: A registrant providing mobile electronic brachytherapy service must, as a minimum:

20-011.14A Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

20-011.14B Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

20-011.14C Perform, at each location on each day of use, all of the required quality assurance checks specified in 180 NAC 20-011.11 to assure proper operation of the device.

20-012 OTHER USES OF ELECTRONICALLY PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE

20-012.01 A person must not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

20-012.01A The applicant or registrant has, at a minimum, provided the Department with:

1. A detailed description of the device and its intended application(s);
2. Facility design requirements, including shielding and access control;
3. Documentation of appropriate training for authorized user physician(s) and qualified medical physicist(s)
4. Methodology for measurement of dosages to be administered to patients or human research subjects;
5. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety
6. Radiation safety precautions and instructions; and
7. Other information requested by the Department in its review of the application; and

20-012.01B The applicant or registrant has received written approval from the Department to utilize the device in accordance with the regulations and specific conditions the Department considers necessary for the medical use of the device.

EFFECTIVE DATE
NOVMEBER 28, 2016

NEBRASKA DEPARTMENT OF
HEALTH AND HUMANS SERVICES

180 NAC 20

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APPENDIX 20-A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. All Therapeutic Radiation Machines

- A. Basic facility information including: name and telephone number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).
- B. All wall, floor, and ceiling areas struck by the useful beam must have primary barriers.
- C. Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic Radiation Machines up to 150 Kv (photons only)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV will submit shielding plans which contain, as a minimum, the following additional information:

- A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;
- B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
- C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth must be noted on the plan and the operator's station at the control panel must be behind a protective barrier sufficient to ensure compliance with 180 NAC 4-005;
- D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
- E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest

area(s) where it is likely that individuals may be present; and

- F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility:
 - 1. If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.
 - 2. Submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic Radiation Machines Over 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons must submit shielding plans which contain, as a minimum, the following additional information:

- A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [i.e.: photon, electron]. The target to isocenter distance must be specified;
- B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
- C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze;
- D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
- E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;
- F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and expected radiation

exposure in both restricted and unrestricted areas; and

- G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility:
 - (1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and
 - (2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron Shielding

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

- A. The structural composition, thickness, minimum density and location of all neutron shielding material;
- B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;
- C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:
 - (1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and
 - (2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the results obtained with the software.
- D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References

- A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of

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X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

- B. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).
- C. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).
- D. NCRP Report 151, "Structural Shielding Design and Evaluation for Megavoltage X and Gamma-Ray Radiotherapy Facilities. (2006).