

641—42.14(136C) General technical requirements for facilities using therapeutic radiation machines.**42.14(1) Protection surveys.**

a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months.

b. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist.

c. The survey shall be performed with the therapeutic radiation machine in a “BEAM-ON” condition using the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation. The survey must verify all of the following:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 37.11(3);

(2) Radiation levels in unrestricted areas do not exceed the limits specified in 641—subrule 37.11(11). In addition to the requirements of subrule 42.14(1), a radiation protection survey shall also be performed prior to any subsequent medical use and at the following frequencies:

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;

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.

d. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations.

e. The survey record shall also include all of the following:

(1) The date of the measurements;

(2) The reason the survey is required;

(3) The manufacturer’s name, model number, and serial number of the therapeutic radiation machine;

(4) The instrument(s) used to measure radiation levels;

(5) A plan of the areas surrounding the treatment room that were surveyed;

(6) The measured dose rate at several points in each area, expressed in microsieverts or millirems per hour;

(7) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area;

(8) The signature of the individual responsible for conducting the survey.

f. If the results of the surveys required by subrule 42.14(1) indicate any radiation levels in excess of the respective limit specified in 641—subrule 37.11(3), the registrant shall lock the control in the “OFF” position and not use the unit, except under either of the following conditions:

(1) If operation is necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding;

(2) Until the registrant has received a specific exemption in writing from the department.

42.14(2) Modification of radiation therapy unit or room before beginning a treatment program.

a. *Survey radiation levels.* If the survey required by subrule 42.14(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—subrule 37.11(11) before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—subrule 37.11(11);

(2) Perform the survey required by 641—paragraph 37.11(12)“a” again; and

(3) Include in the report the results of the initial survey a description of the modifications made and the results of the second survey; or

(4) Request and receive written authorization from the department that authorizes radiation levels in unrestricted areas greater than those permitted by 641—subrule 37.11(11).

b. *Dosimetry equipment.* The registrant shall have a calibrated dosimetry system available for use.

(1) The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).

(2) The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

c. Calibration. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

(1) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements.

1. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph 42.14(2)“b.”

2. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration.

3. The quality assurance check system may be the same system used to meet the requirement in paragraph 42.14(2)“b.”

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the following:

1. The date;

2. The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraph 42.14(2)“b”;

3. The correction factors that were determined;

4. The names of the individuals who performed the calibration, intercomparison, or comparison and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to rule 641—42.3(136C) shall furnish a copy of the records required in subrules 42.11(1) and 42.11(2) to the department within 30 days following completion of the action that initiated the record requirement.

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