

3701:1-67-09 Quality assurance for radiation therapy , simulation and image guidance equipment.

- (A) For therapy equipment subject to this chapter, a qualified medical physicist shall develop a documented quality assurance (QA) program using the appropriate “American Association of Physicists in Medicine” (AAPM) reports or the “National Council of Radiation Protection” (NCRP) report as a basis.
 - (1) The quality assurance program shall:
 - (a) Identify each QA performance test to be performed;
 - (b) Describe the procedures used to complete each QA performance test;
 - (c) Describe the method used to document the results of each QA performance test;
 - (d) Identify the frequency of each QA performance test; and
 - (e) Specify the acceptable action limits and safety tolerance limits for each QA performance test result and the action to be taken when exceeded.
 - (2) Any variation from the identified tests, frequency or tolerance limits specified in the appropriate AAPM or NCRP reports shall be based on a documented history of therapy equipment performance or inherent therapy equipment design and be justified in the quality assurance program.
 - (3) Any QA performance test result exceeding a factor of two from the tolerances in AAPM or NCRP documents shall require immediate action prior to further treatment.
- (B) The handler shall perform QA performance tests in accordance with the written procedures established by the qualified medical physicist and comply with the following:
 - (1) The authorized user and qualified medical physicist shall be immediately notified if any QA performance test result exceeds a safety tolerance limit set by the qualified medical physicist. The cause for a parameter exceeding the safety tolerance limit shall be investigated before the system is used for patient irradiation. The medical physicist in collaboration with the authorized user shall determine whether medical treatment may continue safely or be interrupted until corrected;
 - (2) The handler shall use a dosimetry system described in rule 3701:1-67-07 of the Administrative Code to perform absolute-dose related QA performance tests required by this rule;
 - (3) The handler shall have the qualified medical physicist review and sign the results of each QA performance test within a month of the date that the test was performed, by an individual other than the qualified medical physicist;
 - (4) The handler shall ensure that safety QA tests are performed monthly on the following:

- (a) Electrical interlocks at each external beam radiation therapy room entrance;
 - (b) The "beam-on" and termination switches;
 - (c) All beam indicator lights;
 - (d) Patient audio visual viewing system; and
 - (e) If applicable, electrically operated treatment room doors from inside and outside the treatment room.
- (C) As used in this rule, "calibration" means the determination of the exposure or dose per unit time or absorbed dose per monitor unit (MU) under specified conditions as described in the quality assurance program. Calibration shall be performed:
- (1) Before the first medical use following installation or reinstallation;
 - (2) Annually; and
 - (3) Before medical use under the following conditions:
 - (a) Whenever QA performance test results indicate the radiation output differs by more than five per cent from the calibration value obtained during the most recent annual QA performance tests and the difference cannot be reconciled. Calibration of therapy equipment with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - (b) Following any major mechanical, electrical or software based alterations affecting the radiation source, its housing, power supply or controls or after replacement of the radiation source. If an alteration or replacement does not affect all energies, calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in paragraph (C)(3)(a) of this rule.
- (D) For therapy equipment operating at less than one megavolt (MV):
- (1) The qualified medical physicist shall use NCRP report 69, Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50MeV (1981) for commissioning, initial QA performance testing and to meet the requirements of paragraph (A) of this rule. The term "QA performance test", as used in paragraph (D) of this rule, shall have the same meaning as the term "check" in the NCRP report.
 - (2) Commissioning and initial QA performance testing shall be completed prior to medical use following installation or reinstallation.
 - (3) Commissioning, initial and annual QA performance tests shall be performed by or under direct supervision of a qualified medical physicist.
- (E) For therapy equipment operating at or above one megavolt (MV):
- (1) The qualified medical physicist shall use the "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47 (AAPM report 47)," prepared by "Radiation Therapy Task Group 45" (this publication can be obtained from the

American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) and the manufacturer's contractual specifications as a basis for acceptance testing and commissioning.

- (2) To meet the requirements of paragraph (A) of this rule, the qualified medical physicist shall use:
 - (a) The "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No. 40: AAPM Report No. 46 (AAPM report 46)" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>).
 - (b) "Task Group 142 report: Quality assurance of medical accelerators" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) for therapy equipment provided with asymmetric jaws, multileaf collimation, dynamic or virtual wedges, planar imaging devices, tomographic imaging devices or those used for stereotactic radiosurgery, stereotactic body radiation therapy, total body photon irradiation or intensity-modulated radiotherapy.
 - (c) The "Intraoperative radiation therapy using mobile electron linear accelerators: Report of AAPM Radiation Therapy Committee Task Group No. 72" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) for mobile electron linear accelerator therapy equipment.
 - (d) The "Report of AAPM TG 135: Quality assurance for robotic radiosurgery" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) for robotic radiosurgery therapy equipment.
 - (e) The "QA for helical tomotherapy: Report of the AAPM Task Group 148" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) for helical tomotherapy equipment.
- (3) Acceptance testing, commissioning and baseline QA performance testing shall be completed prior to medical use following installation or reinstallation.
- (4) Acceptance testing, commissioning, baseline and annual QA performance tests shall be performed by or under direct supervision of a qualified medical physicist.
- (5) An independent verification of the calibration of all photon beams and a sample of available electron beams shall be performed annually by:
 - (a) A second radiation expert using a dosimetry system other than the dosimetry system that was used during the annual calibration; or

- (b) A national institute of science and technology traceable third-party dosimetry service or an equivalent method which is capable of measuring doses with an accuracy within five percent.
- (6) Proper operation of each emergency power cutoff switch shall be verified annually. If more than one switch is installed, they may be evaluated on a rotating basis throughout the year.
- (F) For conventional or virtual simulation:
 - (1) The qualified medical physicist shall use the "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No. 40: AAPM Report No. 46 (AAPM report 46)" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) to meet the requirements of paragraph (A) of this rule for a conventional simulator; or
 - (2) The qualified medical physicist shall use the "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 (AAPM report 83)" (this publication can be obtained from the American association of physicists in medicine, One Physics Ellipse, College Park, MD 20740, telephone (301) 209-3350, <http://www.aapm.org/pubs/reports>) for acceptance testing, commissioning and to meet the requirements of paragraph (A) of this rule for a virtual simulator.
 - (3) Acceptance testing, commissioning, initial QA performance testing, annual QA performance testing and semiannual (if appropriate) QA performance testing shall be performed by or under the direct supervision of a qualified medical physicist.
- (G) For therapy equipment used for IMRT, patient specific treatment QC shall be performed before the first fraction is delivered unless extenuating circumstances are documented by the medical physicist. If a direct measurement for individual plans is not performed, the checks shall include both a dose calculation second check and a method to validate patient plan transfer and deliverability to the treatment unit.
- (H) The handler shall maintain a record of each QA performance test result for three years and each calibration for the duration of the registration. The records shall include:
 - (1) The date of the QA test or calibration;
 - (2) The manufacturer's name, model number, and serial number of the therapy equipment;
 - (3) The manufacturer's name, model numbers and serial numbers for the instrument(s) used to measure the radiation output of the therapy equipment; and
 - (4) The signature of the individual who performed the QA performance test or calibration.

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