20/3020/2010

7 April 2011

TRANSLATION. ORIGINAL TEXT IN FINNISH.

Holders of safety licences

Acceptability requirements for radiotherapy equipment

According to the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000, Section 30), the procedures involving exposure to radiation shall be performed by appropriate equipment. Furthermore, the decree specifies that the requirements and acceptability criteria for specific equipment functions for radiation safety shall be confirmed by the Radiation and Nuclear Safety Authority (STUK).

This decision confirms the enclosed acceptability criteria, i.e. the acceptability requirements for radiotherapy equipment.

This decision is valid as of 5 April 2011.

Deputy Director General,
Director Lasse Reiman

Director Eero Kettunen

Appendix Acceptability requirements for radiotherapy equipment

Acceptability requirements for radiotherapy equipment

The acceptability requirements denote the minimum requirements or acceptability limits imposed on the performance capacity of the equipment. If the acceptability requirements are not met, one of the following measures must be taken:

- Corrective actions must be implemented in order to restore the performance to an acceptable level.
- The use of the device must be restricted in order to prevent the exceeding of the limiting value from affecting the treatment.
- The device must be decommissioned.

The acceptability criteria are usually not optimal values for equipment performance. As responsible parties (operators) purchase new equipment, perform acceptance tests and verify the quality of the equipment during use, they should apply stricter requirements, which may be based, for example, on equipment vendors specifications or the performance limiting values suggested in the equipment standards.

The following table presents the acceptability criteria for accelerators, brachytherapy equipment (afterloading radiotherapy equipment) and simulators used in radiotherapy. The results of the performance measurement depend on the measurement conditions and may also depend on the method of measurement. Unless otherwise stated in the reference column, the acceptability requirements stated in the table correspond to the measurement conditions stated in bibliographic reference [1].

Bibliographic references

[1] International Electrotechnical Commission (IEC): Medical electrical equipment. Medical electron accelerators – Functional performance characteristics, International standard IEC 976.

[2] American Association of Physicists in Medicine (AAPM): AAPM code of practice for radiotherapy accelerators: Report of AAPM Radiation Therapy Task Group No. 45, Med. Phys. 21 (7), 1093–1121, July 1994.

[3] Radiation and Nuclear Safety Authority: Sädehoidon annosmittaukset. Ulkoisen sädehoidon suurenergisten fotoni- ja elektronisäteilykeilojen kalibrointi (Determination of absorbed dose to water in radiotherapy. Calibration of high energy photon and electron radiation beams in external radiotherapy). STUK-STO-TR 1, 2005.

[4] Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer. IAEA-TECDOC-430, IAEA 2004.

Table. Acceptability requirements for the performance of radiotherapy equipment.

Characteristic	**Reference**	**Largest allowed deviation**
Mechanical characteristics: accelerators and simulators		
Accuracy of angle indicator		2°
Accuracy of numeric field size indicator		2 mm
Alignment of the light field and the radiation field		
photon radiation		2 mm
electron radiation		3 mm
Accuracy of field centre point indicator		2 mm
Radius of the mechanical isocentre		2 mm
Accuracy of the optical distance indicator		
at the isocentre		2 mm
elsewhere		4 mm
Accuracy of treatment table movements		
vertical movement		5 mm
longitudinal and lateral movement		3 mm
rotation, deviation from the isocentre		2 mm
Accuracy of the patient alignment lasers		
at the isocentre		2 mm
elsewhere, at most ±30 cm from the isocentre		3 mm
Dose monitoring: accelerators		
Repeatability		0.5%
Linearity (only at the dose rate that will be used)		1% or 20 mGy
Dependency from the gantry and beam limiting device angle		2%
Stability of the calibration during a day		2%
Radiation beam characteristics: accelerators		
Radius of the radiation isocentre		2 mm
Flatness of the field	[2]	
for photon and electron radiation ≥ 6 MeV		3%
for electron radiation less than 6 MeV		6%
Symmetry		
for photon radiation		3%
for electron radiation		5%
Penumbra		
for photon radiation		8 mm
for electron radiation		15 mm
Dose planning system for accelerators		
Difference between calculated and measured dose at reference point	[3]	3%
Difference between calculated and measured dose within the planned target area for photon radiation in water equivalent material	[4]	5%/5 mm
Characteristics of an afterloading device		
Source location accuracy		2 mm
Timer error		3% of treatment time or at most 1 s