9/3020/2013

5 July 2013

TRANSLATION. ORIGINAL TEXT IN FINNISH.

Safety licence holders for nuclear medicine practices

Acceptability requirements for equipment used in nuclear medicine practices

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 using equipment suited to the said purpose. Furthermore, the decree specifies that the requirements and criteria of acceptability for specific equipment functions to be considered from the point of view of 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 equipment used in nuclear medicine.

This decision is valid as of 1 August 2013.

Acting Director General,
Director Petteri Tiippana

Director Eero Kettunen

Appendix Acceptability requirements for equipment used in nuclear medicine practices

ACCEPTABILITY REQUIREMENTS FOR EQUIPMENT USED IN NUCLEAR MEDICINE PRACTICES

The acceptability requirements denote the minimum requirements or acceptability limits that are imposed on the performance characteristics of the equipment when it is used [1]. No later than at the time the equipment no longer meets an acceptability limit, the equipment must be repaired in a way that restores its performance characteristics to comply with the acceptability limit. Otherwise, it must be decommissioned. If necessary, it is possible to continue the use of such equipment temporarily provided that the use is restricted in a way that enables the operation of the equipment according to the acceptability requirements.

The acceptability requirements typically concern the precision of the settings and the operating condition of the equipment. They are not limit values for optimal equipment performance. As responsible parties (parties running a radiation practice) purchase new equipment, perform acceptance tests and inspect the quality of the equipment, they should apply stricter requirements, which may be based, for example, on equipment specifications or the performance tolerances presented in the equipment standards.

When evaluating the results of performance measurements, it should be considered that the conditions of the measurement and the methods used may affect the results. More information on appropriate procedures for determining the performance characteristics is available in the bibliographic references.

The equipment used in nuclear medicine as well as the accessories and instruments related to its use shall meet the acceptability requirements presented in this decision (see also the Decree of the MSAH 423/2000 [2], Section 30, and Guide ST 6.3 [3]). The X-ray equipment related to nuclear imaging equipment shall also meet the acceptability requirements for X-ray equipment used in health care [4], where applicable. Furthermore, the regulations concerning medical devices and accessories [5] apply to the equipment used in nuclear medicine.

The results of measurement that have been achieved under the conditions described in STUK's "Quality control guidance for nuclear medicine equipment, Advice from STUK 1/2010" [6] and by using the methods of measurement described therein are compared to acceptability requirements shown in Tables 1-6. Insofar as the acceptability requirements are based on earlier publications, the reference to the source can be found in the reference column.

Table 1 Acceptability criteria for the gamma camera.

Gamma camera		
Characteristic	**Largest allowed deviation or result**	**Reference**
Smoothness • integral irregularity of the useable view (UFOV)	7%	[1]
Centre of rotation	single pixel	[1]
Sensitivity • difference between the sensitivities of different detectors	10%	[1]
Spatial resolution • Full Width at Half Maximum (FWHM)	≤ 6 mm	[1]
Spatial resolution for whole-body imaging • Full Width at Half Maximum (FWHM)	≤ 12 mm	[7]

Table 2 Acceptability criteria for the activity meter.

Activity meter (dose calibrator)		
Characteristic	**Largest allowed deviation**	**Reference**
Linearity	±5%	[1]
Reproducibility (constancy)	±5%	[1]
Accuracy at gamma energies above 100 keV at gamma energies below 100 keV	 ±5% ±10%	 [1] [8]

Table 3 Acceptability criteria for the PET camera.

PET		
Characteristic	**Largest allowed deviation or result**	**Reference**
Quantitativeness of PET images (SUV measurement)	10%	[6]
Smoothness Variation of baseline areas of interest in the NEMA image quality test [10] • standard deviation/average	10%	[7]
Spatial resolution • Full Width at Half Maximum (FWHM)	≤ 8 mm	[7]

Table 4 Acceptability criteria for hybrid imaging equipment.

Hybrid imaging equipment* SPECT-CT and PET-CT		
Characteristic	**Largest allowed deviation**	**Reference**
Geometric positions of the nuclear imaging device and CT device in relation to each other	1 pixel (in the PET or SPECT image)	[1]

*In addition to this decision, the acceptability criteria for X-ray equipment apply to CT equipment, where applicable.

Table 5 Acceptability criteria for gamma detectors used during operations.

Gammaprobe/Gamma detectors used during operations		
Characteristic	**Largest allowed deviation**	**Reference**
Constancy of sensitivity	20%	[7]

Table Acceptability criteria for the gamma counter.

Gamma counter (well crystal)		
Characteristic	**Largest allowed deviation**	**Reference**
Constancy	5%	[7]

References

[1] Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy. Radiation Protection No 162, European Union 2012.
[2] Decree of the Ministry of Social Affairs and Health on the medical use of radiation 423/2000.
[3] Guide ST 6.3, Radiation safety in nuclear medicine, 14 January 2013
[4] Acceptability requirements for X-ray equipment used in health care, 2013
[5] Medical Devices Act (629/2010)
[6] Quality control guidance for nuclear medicine equipment, Advice from STUK 1/2010
[7] Recommendation from the expert team preparing STUK's decision.
[8] National Physics Laboratory, A National measurement good practise guide No. 93
http://publications.npl.co.uk/npl_web/pdf/mgpg93.pdf
[9] NEMA Standards Publication NU 2-2007. Performance Measurements of Positron Emission Tomographs. Rosslyn: National Electrical Manufacturers Association; 2007.