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Quality Control of Nuclear Medicine Equipment – Definition of Action Levels and Tolerance Limits

Recommendation by the German Commission on Radiological Protection

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Qualitätskontrolle von nuklearmedizinischen Geräten - Festlegung von Reaktionsschwellen und Toleranzgrenzen

Empfehlung der Strahlenschutzkommission

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1 Introduction

Physical-technical quality assurance is an essential component of optimised radiological protection (ALARA), also in the field of nuclear medicine, and its general application is therefore stipulated in the current drafts of the Basic Safety Standards issued by IAEA and Euratom (IAEA 2010, EC 2010 b). Pursuant to §83 subsection (5) of the Radiological Protection Ordinance (*Strahlenschutzverordnung*), all equipment used in nuclear medicine for examination or treatment purposes must be subject to internal quality control. At the technical level, all equipment is required to undergo an acceptance test when it is put into service (and, if necessary, after major modifications) and regular constancy tests afterwards. This serves to ensure proper functioning and to detect, without delay, deviations from an initial or target value (reference value) during operation (RL-StrlSchMed 2002, Busemann et al. 2010).

A further aim of quality control is not only to detect but also to react appropriately to errors in order to prevent unnecessary radiation exposure of the patient or inaccurate diagnoses. For that reason, it is axiomatic that a constancy test must be performed, even at short notice, whenever there is cause to suspect any malfunction in equipment operations.

Quality control of nuclear medicine equipment mainly provides quantitative data; however, there are not yet any binding rules governing action levels and tolerance limits. The EU is currently attempting, in its Draft for updating Radiation Protection RP 91 (EC 2010 a), to establish minimum acceptability criteria. Based on existing formal national and international standards and recommendations and on the proposals made by the Permanent Conference of State Departments for Clinical Audit in Radiation Protection (ZÄS) and relevant literature (ZÄS 2009, Eckardt et al. 2009), the Commission on Radiological Protection (SSK) has now produced a recommendation which, on the one hand, reflects the current state of technology, and, on the other, ensures that as far as possible, the quality of the evaluation of findings is not affected by fluctuations in the measuring equipment used. The proposed values for action levels and tolerance limits would allow users and manufacturers to implement the quality assurance system described in the amended guideline on radiological protection in the medical field (*Richtlinie "Strahlenschutz in der Medizin"*).

To avoid any conflict arising between the quality requirement and cost effectiveness factors, it is necessary to consider the specific field of application of the device or system. For example, more stringent requirements must apply for gamma cameras used for SPECT examinations as regards yield, uniformity and image quality than for equipment used solely for simple planar examinations such as thyroid scintigraphy. This observation and the definition of relevant action levels und tolerance limits mean, for example, that gamma cameras which no longer meet the requirements of SPECT technology can still be used for planar imaging, with due consideration for the existing limitations. In conceptual terms, this approach was also described in the SSK's recently published recommendation on physical-technical quality assurance in radiotherapy (SSK 2010).

The manufacturers of systems used in nuclear medicine are increasingly recognising the need to supply and integrate quick and simple testing procedures for quality control and the appropriate hard- and software. Modern PET and hybrid systems in particular generally have built-in daily control routines, which enable the user to check the entire system; they also detect any exceedance of action levels or tolerance limits and automatically log the findings. For that reason, the present recommendation does not specify action levels or tolerance limits for these particular systems.

2 Acceptance tests

Acceptance tests are required by the user after installation, takeover and substantial repair (e.g. replacement of major components of a gamma camera head). They are generally performed by the manufacturer or supplier or a medical physics expert in collaboration with the user. During the acceptance test, intensive measurements are performed on the basis of technical norms and recognised standards, such as NEMA publications or IAEA "Tecdocs", in order to determine whether the system concerned complies with the required specifications. Data for optimisation of examination and evaluation parameters are also obtained. For new purchases, it is advisable to incorporate the relevant manufacturer's specifications and acceptance test into the terms of the purchase contract. The European Commission has published criteria for acceptability of installations (EC 1997) which are currently being revised and updated (EC 2010). As part of the acceptance test, the reference values for the constancy tests are determined with the user's measurement methods and instruments, generally on the basis of the relevant standards.

3 Constancy tests

The starting point for the constancy test is provided by reference values which are determined by means of an acceptance test. To that end, on a properly functioning and optimised system, a test is carried out with the methods, parameters and measuring instruments to be used during the constancy test. The required frequency of constancy tests is stipulated in the guideline on radiological protection in the medical field (*Richtlinie "Strahlenschutz in der Medizin"*) and in the relevant standards. A test must be performed whenever there is cause to suspect any malfunction in equipment operations.

The documentation of the constancy test is produced by logging the identified values in a measurement report, with images of the findings as far as possible. Both the images and the documentation should include not only the findings but also the action levels, tolerance limits, all the main system settings and if appropriate the measurement equipment used, attribution of sources, and activities. Records of the results of evaluations or reconstructions should show the variables used; for example, when checking SPECT non-uniformity and resolution, the image processing, type of reconstruction and parameters used must be discernable.

The documentation process, including the images, should ensure that any variation from the reference values can be easily recognised. For example, when depicting non-uniformity, its variation should be visible in the camera image.

In quality control for activimeters, it must be ensured, first and foremost, that the value shown, within the range of permissible uncertainty, corresponds to the correct activity. Regular comparative measurements by the user and the manufacturer with an ionisation chamber test source with a long half-life serve this purpose (see DIN 6855-11). Modern computer-based equipment allows the user to input the radionuclide factors themselves. This allows accuracy to be adapted to the different geometries and shielding conditions of the vials and syringes being used. To determine these radionuclide factors, certified radionuclide solutions are used, for example, or follow-up measurements can be taken on appropriate quality-assured systems.

High-quality image documentation is essential, both for the findings of examinations performed on patients and for the evaluation of the constancy test. Moreover, for archiving of

print-outs, image stability must be guaranteed for the storage periods stipulated in the Radiological Protection Ordinance (*Strahlenschutzverordnung*) (10 years for diagnostics; 30 years for therapeutics). In order to assess the imaging accuracy, resolution and quality of a documentation system, appropriate test images must be available (e.g. SMPTE Standards provide information about the test images which may be appropriate for the specific purpose) and used on a regular basis. These show changes and variations compared with the information presented on the diagnostic monitor.

4 Action levels

Action levels are values used in constancy tests. If they are exceeded, an investigation must be conducted in the framework of the internal quality assurance system into the underlying cause, and a previously defined course of action is triggered. For example, this may entail a radiological protection supervisor or consultant medical physics expert providing information for a decision on the further procedure, calibration routines being performed, or the service team being called. The purpose of action levels is, in particular, to prevent tolerance limits being exceeded during normal operation. At the same time, they are important tools for optimising radiation protection.

5 Tolerance limits

When tolerance limits are exceeded, the use of the equipment on patients is not allowed or only possible with the restrictions stipulated by the radiological protection supervisor until the cause has been found and the problem solved. Violations of tolerance limits, their causes and consequences must be documented in the log book stipulated in §34 of the Radiological Protection Ordinance (*Strahlenschutzverordnung*). Action levels and tolerance limits may be set at the same values, especially for older equipment.

Recommendation

The appropriate action levels and tolerance limits should ideally be established on the basis of reference values during the acceptance test, other system tests or from the statistical fluctuation of a measurement series determined by a medical physics expert with reference to this recommendation. The determination should take place in such a way that permissible deviations and fluctuations do not significantly affect the findings of an examination, adversely impact on image quality or, more generally, call the informative value of a measurement into question. The tolerance limits proposed here can of course be modified with a view to improving quality, mainly if the equipment or examination method so requires, or in light of new scientific findings.

The SSK recommends that the following tables be used as the basis for quality assurance in nuclear medicine:

Table 1: Planar Gamma Cameras

Test parameters	**Reference value (RV)** **Action levels (AL)**	**Tolerance limits** **(TL)**	**Explanations/comments**
Background	RV = mean of at least 10 measurements with > 1000 impulses AL = RV ± 20 %	TL = RV ± 50 %	In the event of exceedance of the AL occurring, measurement of yield must be performed.
Energy spectrum	RV = gamma energy of the nuclide used AL = RV ± 5 %	TL = AL	On equipment which has an automatic correction facility, these recommendations apply to the correction value.
Yield/sensitivity	RV from acceptance test or most recent half-yearly test AL = RV ± 5 %	TL = RV ± 10 %	Change in yield must be monitored and documented throughout the camera's operating time (crystal). With uniformity correction, yield reduction to less than 20 %.
Non-uniformity	RV = extrinsic (with collimator) integral non-uniformity in the UFOV (useful field of view) from acceptance test or most recent half-yearly test AL = RV + 0.5 RV (max. AL = 8 %)	TL = 8 %	When redefining the parameters (matrices) for non-uniformity correction, the influence of the yield must always be considered; realignment of the gamma camera may be required. For measurements without collimator, TL decreases according to the collimator's contribution to non-uniformity.
Spatial resolution	RV = Image documentation from acceptance test AL = TL	4 mm without collimator 6 mm with collimator	Applies to visual evaluation of a lead strip or orthogonal hole phantom.
Linearity	RV = Image documentation from acceptance test AL = TL	No visible deterioration compared with RV	Generally associated with non-uniformities.
Magnification	RV = Distance between point sources or pixel size in acceptance test AL = RV ± 5 %	TL = AL	With digital cameras, pixel size is used.
Whole-body accessory	Magnification: RV = Distance between point sources or pixel size in acceptance test AL = RV ± 5% Spatial resolution: RV = Image documentation from acceptance test	TL = AL No visible deviation from RV	

Table 2: SPECT Gamma Camera (for test parameters not listed, Table 1 applies)

Test parameters	**Reference value (RV)** **Action levels (AL)**	**Tolerance limits** **(TL)**	**Explanations/comments**
Tilt angle	RV = angle display AL = RV ± 2°	TL = AL	Single head systems only; for multi-headed systems, the resulting deviation from the centre of rotation is the relevant factor.
Yield/sensitivity	RV from acceptance test or most recent half-yearly test AL = RV ± 5 %	TL = RV ± 10 %	Change in yield must be monitored and documented throughout the camera's operating time (crystal). With uniformity correction, yield reduction to less than 20 %.
Non-uniformity	RV = extrinsic (with collimator) integral non-uniformity in the UFOV (useful field of view) from acceptance test or most recent half-yearly test AL = RV + 0.5 RV (max. AL = 5 %)	TL = 5 %	When redefining the parameters (matrices) for non-uniformity correction, the influence of the yield must always be considered (variation ≤ 20 %); realignment of the gamma camera may be required.
Centre of rotation	RV = 0 mm AL = RV+1.5 mm or AL = RV+1Pixel	TL = 2 mm	The values apply with offset correction; here, TL (without correction) ≤ 6mm
Tomographic uniformity and contrast with volume phantom	RV from acceptance test or most recent half-yearly test AL = TL	No relevant deterioration of reference image	Reconstruction: iteration or ramp with filtered back projection When using Jaszczak phantom, at least 3 hollow spheres must be discernable with certainty; no ring artifacts visible.

Table 3: Activimeters

Test parameters	**Reference value (RV)** **Action levels (AL)**	**Tolerance limits** **(TL)**	**Explanations/comments**
Background	RV = Displayed value when put into service, without background correction, using sample holder AL = RV ± 50 %	TL = RV ± 100 %	Background always without correction. With digital activimeters, measurement in all nuclide settings is dispensed with.
Responsiveness	RV from calibration table from the manufacturer or MPE AL = RV ± 5 %	TL = AL	Measurement with correction. With digital activimeters, measurement in all nuclide settings is dispensed with. Recalibration with metrological testing should take place at least every 6 years.
Linearity	RV = Regression line through start value AL = ± 5 % deviation from the regression line (or the computational nominal value) (see DIN 6855-11)	TL = AL	As the starting activity using the decay method, at least 60 % of the elution activity of the strongest generator (first eluate) must be used, with measurements performed up to 1 MBq. Linearity can also be determined using serial dilution. The starting activity corresponds to the first eluate, with the loss of activity for the dilution amounting to 10 - 15 %. Two samples should be prepared for each decimal power.
Molybdenum breakthrough	AL = TL	TL = 0.1 % molybdenum in the eluate. When measuring with shielding in the ^{99m}Tc setting, TL = 0.04 % of the measurement value without shielding	The first eluate after receipt should be measured for molybdenum breakthrough. If generators are in use for more than14 days after the first elution, further testing of molybdenum breakthrough should be carried out.

Table 4: Probe Measuring System / Well Counter for use in in-vivo examinations

Test parameters*	**Reference value (RV) Action levels (AL)**	**Tolerance limits (TL)**	**Explanations/comments**
Background	RV = mean of at least 10 measurements with > 1000 impulses AL = RV ± 20 %	TL = RV ± 50 %	Background in all energy settings used.
Energy window	For four-channel analysers and measuring systems with energy display RV = Gamma energy of the nuclide used AL = RV ± 5 %	TL = AL	
Responsiveness	RV = mean of at least 10 measurements with > 1000 impulses AL = RV ± 5 %	TL = AL	When using an energy-appropriate test source, checking of energy window during daily measurement of equipment without an energy display can be dispensed with. The energy deviations must then be taken into account in the limits for responsiveness.
Well factor	RV = Value from previous measurement AL = RV ± 5 %	TL = RV ± 10 %	Well factor = conversion factor of applied activity in the measurement value of well geometry. If the action level is reached, measurement should be repeated shortly.

***** Further tests to be carried out as part of the acceptance test and when searching for errors.

Table 5: Intraoperative gamma probes

Test parameters *	**Reference value (RV) Action levels (AL)**	**Tolerance limits (TL)**	**Explanations/comments**
Background	RV = mean of at least 10 measurements AL = RV ± 20 %	TL = RV ± 50 %	
Responsiveness	RV = mean of at least 10 measurements RS = RV ± 5 %	TL = RS	^{57}Co should be used as the test source.

***** Further tests to be carried out as part of the acceptance test and when searching for errors.

Please note: The above tables are based on the references listed below, including good practice established in existing quality assurance systems. The Commission on Radiological Protection (SSK) emphasises that the validity of the proposed values must be regularly reviewed and if necessary modified, with a view to optimisation, as new findings become available.

References

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-2 Konstanzprüfung von Einkristall-Gammakameras zur planaren Szintigraphie und zur Einzelphotonen-Emissions-Tomographie mit Hilfe rotierender Messköpfe (Januar 2005)

-4 Konstanzprüfungen von Positronen-Emissions-Tomographen (PET) (November 2004)

-11 Aktivimeter (Mai 2009)

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DIN EN 61675 Bildgebende Systeme in der Nuklearmedizin - Merkmale und Prüfbedingungen

-3 Gamma-Kameras mit Ganzkörpereinrichtung (Dezember 1999)