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Comparative analysis of equipment performance in nuclear medicine

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ABSTRACT

To ensure satisfactory equipment performance, image reliability and accurate diagnosis a set of measurements and analysis named as quality control (QC) has to be established. QC is a routine practice where the essential equipment performance or procedure is evaluated by comparing the results to a predefined acceptable range. Currently there are 448 Nuclear Medicine Services (NMS) in Brazil that have to comply with the standards and regulations stablished by Brazilian regulatory agencies, the Comissão Nacional de Energia Nuclear (CNEN) and the Agência Nacional de Vigilância Sanitária (ANVISA). Both National authorities, CNEN and ANVISA, must control and ensure compliance with their national regulations including quality control tests of equipment be fulfilled by all NMS operating in Brazil. However, these standards do not establish minimum performance requirements for most of the tests and do not guarantee the required quality to the population health care. This paper aims to evaluate and analyze the performance limits of the quality control tests in nuclear medicine practice requested in Brazilian standards and to compare them with available requirements addressed in international recommendations. Regarding performance limit evaluation many of the requested tests do not address a methodology or minimum performance values to ensure what is considered satisfactory in a quality control test. It was found that Brazilian NMS standards need revision when compared to international recommendations.

Palavras-chave: performance, quality control, nuclear medicine.

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1. INTRODUCTION

In Brazil there are currently 448 licensed Nuclear Medicine Services (NMS) in operation [1]. In February 2019 there were approximately 120 NMSs with therapeutic rooms for Iodine-131(^{131}I) therapy, when the patient must remain isolated until administered radioactive material decay. There are also other therapies in the country that do not require hospitalization, such as those using Samarium-153 (^{153}Sm), Yttrium-90 (^{90}Y), Lutetium-177 (^{177}Lu) and Radio-223 (^{223}Ra) [2].

In these NMS distributed around the country, there are 939 gamma cameras and single photon emission computed tomographs (SPECT), about 10 single photon emission computed tomographs associated with X-ray computed tomographs (SPECT/CT), 150 Positron Emission Tomographs associated with X-ray Computed Tomographs (PET/CT) and 18 cyclotrons for radiopharmaceutical production [2].

In terms of licensing and control, there are two regulatory bodies for NMS, the Comissão Nacional de Energia Nuclear (CNEN) and the Agência Nacional de Vigilância Sanitária (ANVISA), both with legal authority to ensure compliance with their standards and regulations [3, 4].

To ensure good equipment performance, image reliability and to promote accurate diagnosis and therapy, a set of measurements and analysis, known as quality control (QC) is established. QC may be defined as an established set of measurements and analysis designed to ensure that the performance of a procedure, equipment or instrument is within a predefined acceptable range [5].

The Brazilian standard CNEN NN-3.05[3] requires NMS to perform quality control tests for Scintillation Camera, Iodine Uptake Probe, Gamma Probe, Positron Emission Tomography and Activity Meter (Dose Calibrator). In addition, NMSs must also comply with ANVISA Resolução de Diretoria Colegiada – RDC 38 (Resolution of the Collegiate Board) [4]. This standard also requires compliance with quality assurance procedures in nuclear medicine, describing acceptance and quality control tests to be performed and their frequencies [3, 4].

The Associação Brasileira de Normas Técnicas (ABNT) is responsible for preparing Brazilian Standards (ABNT/NBR) through Brazilian Committees (ABNT/CB) and its Study Committees (ABNT/CE). These standards are related to internationally accepted guides and technical principles and are based on a technical structure and multidisciplinary auditors, ensuring credibility, ethics and

recognition of the services provided. ABNT has been participating in International Electrotechnical Committee (IEC) standards group and adapting the documents (standards and technical reports) for radionuclide imaging devices and other instrumentals applied to Nuclear Medicine practice. As these documents have their relevance, they will be considered in this study [6].

In this study the Brazilian standards and regulations regarding quality control test and their performance limits, when stablished, are evaluated comparing with international recommendations. In this way, the lack of national regulation improvement is emphasized, aiming to promote the quality assurance for the population health care.

2. MATERIALS AND METHODS

This study was conducted by comparing published international and Brazilian standards regarding requirements for the most quality control tests applied to nuclear medicine. Quality control testing is required in several regulatory documents and recommendations to ensure good equipment performance. Each Brazilian and international standard addresses a particular quality control test for nuclear medicine instruments. All the requirements were compared and related to minimum performance values, as possible. To performed this comparison and analysis of the Brazilian standards and regulations from CNEN and ANVISA: CNEN NN 3.05 [3] and ANVISA RDC 38 [4] standards were conducted.

In addition, Brazilian ABNT standards: ABNT/IEC/TR 61948-1:2018 [7]; ABNT/NBR/IEC 61303:2014 [8]; ABNT/NBR/IEC 61675-2:2018[9] and ABNT/NBR/IEC 61675-1:2016 [10] were also analyzed.

Among international recommendations, documents from International Atomic Energy Agency (IAEA), from American Association of Physicists in Medicine (AAPM) and from US National Electrical Manufacturers Association (NEMA) were included in this analysis. The AAPM uses IAEA documents as basis for achieving QC; in this way, IAEA applies IEC standards, international organization for standardization of electrical, electronic, and related technologies. Some of its standards are developed together with International Organization for Standardization (ISO) [12, 13, 21].

From IAEA, TECDOC-602 [11] provides detailed guidance on the quality control of the various instruments.

From AAPM, Report No. 181 [12] describes the use of radionuclide ionization chamber to measure the activity of medium and high-energy beta-gamma, positron-emitting and beta-emitting radionuclides; Report No. 6 [13] sets requirements for scintillation chambers, and the Report No. 177 [19] that establishes requirements for testing these image systems.

Other relevant documents used in QC are from the Manufactures Association, NEMA, providing uniform criteria for the measurement and reporting performance parameters, as NEMA-NU 1-2007 [14], NEMA NU 2-2007 and NEMA NU 3-2004 [16].

In 2009, with the development of new hybrid technologies that combined medical diagnostic modality of PET and CT, the IAEA published two documents named Health Series, HHS No. 1 [17] and HHS No. 6 [18]. These IAEA Human Health Series publication provide information, guidelines and codes of practice for quality assurance control.

3. RESULTS AND DISCUSSION

3.1 Probes

There are two probes in nuclear medicine instrumentation: Gamma Probe to perform radiosurgery and Uptake Probe to verify iodine uptake essay. Table 1 shows the comparison of Uptake Probe and Gamma Probe minimum performance requirements. It is worth remembering that the comparisons were made based on what is required for quality control testing by Brazilian standards where for both Gamma Probe and Uptake Probe, only one test is required. Besides, only CNEN NN 3.05 [3] requires testing CQ for these devices. The ANVISA RDC 38 [4] standard only states in item 4.5.7 that the health service that performs radio-guided surgeries must have access to an image acquisition system and a portable gamma radiation detector with a surgical probe.

Verifying tolerance criteria for uptake probe testing, CNEN NN 3.05 [3] describes the acceptance value as a percentage of chi-square values, not describing under which conditions these values could be acceptable. ANVISA RDC 38 [4] has no acceptable limits. The standard

ABNT/IEC/TR 61948-1 [7] describes an acceptable value for these tests in terms of chi-square, but considering absolute values, unlike CNEN NN 3.05 [3].

International recommendations adopt different acceptance values for the Uptake Probe QC test. TECDOC 602 [11] adopts a 95% confidence interval in a sample with 10 measurements and 9 degrees of freedom; its tolerance value is in terms of chi-square in absolute values between 3.32 and 16.92. NEMA NU 3-2004 [16] considers performing 20 measures and 19 degrees of freedom with a 95% confidence interval and its chi-square tolerance in absolute values is between 6.84 and 30.14.

There is a similarity of chi-square values for the documents ABNT/IEC/TR 61948-1 [7] and IAEA TECDOC 602 [11], both have the tolerance criteria in absolute values, but the national document does not address under what conditions these values could be considers acceptable, different from international recommendations.

Table 1: Performance limits or tolerance criteria for Uptake Probe and Gamma Probe [3, 4, 7, 11, 16].

Uptake Probe					
Acceptance Limits / Tolerance Criteria for QC testing					
	Brazilian Standards			**International Recommendations**	
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/ IEC/TR 61948-1**	**IAEA TECDOC-602**	**NEMA NU 3-2004**
Uptake Probe Test	(5%< $\chi 2$ <95%)	NR[a]	(3,3 < $\chi 2$ <16,9)	For a sample size of 10, and thus 9 degrees of freedom, the 95% confidence limits for $\chi 2$ are respectively 3.32 and 16.92.	Short-term stability - For a sample size of 20 with 19 degrees of freedom, the 95 % confidence levels for chi-square are 6.84 and 30.14.
Gamma Probe					
	Brazilian Standards			**International Recommendations**	
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/ IEC/TR 61948-1**	**IAEA TECDOC-602**	**NEMA NU 3-2004**
(Repeatability) Constance Test	σ <10%	NR[a]	(3,3< $\chi 2$ <16,9)	For a sample size of 10, and thus 9 degrees of freedom, the 95% confidence limits for $\chi 2$ are respectively 3.32 and 16.92.	Short-term stability - For a sample size of 20 with 19 degrees of freedom, the 95 % confidence levels for chi-square are 6.84 and 30.14.

NR[a]: Not Required
σ: standard deviation (sigma)
$\chi 2$: chi-square: result of the statistical test

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Table 2 presents other operational check and acceptance/reference tests requested by IAEA TECDOC-602 [11] and not included in national standards. Several tests are broken down in this recommendation, in addition to those following the Brazilian standard. Another 16 tests are presented that can evaluate the instrument and guarantee the quality control effectiveness, where four have a limit/acceptance criterion to be considered during the instrument evaluation. This document, despite published in 1991, presents a very complete information describing tests proposal, materials, procedures, in some cases more than an alternative method for each test, analysis method, observations to be considered, interpretation of results, conclusion and some acceptability limits.

NEMA NU 3-2004 [16] also describes 13 further tests for *in vivo* counting system evaluation as shown in Table 3 and addresses acceptance/reference and operational check tests. Two tests have a performance limit being considered during equipment acceptance/reference, but no operational check tests have established the performance limits.

The ABNT IEC/TR 61948-1 [7] document mentions other tests to be performed on the counting systems, which are three operational check tests and two acceptance/reference tests. None of these has tolerance limits, as shown in table 4.

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Table 2: Other acceptance and reference tests and operational checks for *in vivo* and *in vitro* counting systems QC (IAEA-TECDOC 602) [11].

Uptake Probe and Gamma Probe	
QC test	**Acceptance Limits / Tolerance Criteria**
Physical inspection[a]	NR[a]
Scaler-time/Ratemeter[a]	NR[a]
Energy calibration[a]	NR[a]
Energy Resolution (% FWHM)[a]	NR[a]
Sensitivity[a]	NR[a]
Energy Response Linearity[a]	NR[a]
Integral background radiation rate test[a]	≤ 20%
Linearity activity response [a]	≤ 1%
Preset Analyzer Facilities[a]	<10%
Linearity of Response Recorder [a,c]	NR[a]
Recorder Graphics Unit Test[a,c]	NR[a]
Check of Collimator and Probe Mountings[b,c]	NR[a]
Check of Record Function[b,c]	NR[a]
Check of Analyzer Peak Setting[b]	NR[a]
Check of Probe Sensitivity [b,c]	± 4%.
Check of background radiation counting rate[b]	± 20%.

a: Acceptance and reference tests

b: Operational check tests

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NR[a]: Not Required
C: Only for "*in vivo*" counting system

Table 3: Other acceptance and reference tests and operational cheks for *in vivo* counting systems (NEMA NU 3-2004) [16].

Uptake Probe and Gamma Probe	
QC test	**Acceptance Limits / Tolerance Criteria**
Sensitivity[b]	NR[a]
Visual and Physical Inspection[b]	NR[a]
Source of Power[b]	NR[a]
Sensitivity in Air[a]	NR[a]
Sensitivity in a scatter medium[a]	NR[a]
Sensitivity through side air protection[a]	NR[a]
Sensibitivity to Scatter[a]	<10%
Spatial Resolution in a Scatter Medium[a]	NR[a]
Volume Sensitivity to Distributed Activity in a Scatter Medium[a]	NR[a]
Count Rate Capability in a Scatter Medium[a]	± 20%
Angular Resolution in a Scatter Medium[a]	NR[a]
Energy Resolution[a]	NR[a]
Side and Back Shielding[a]	NR[a]

a: Acceptance and reference tests
b: Operational check tests/CQ
NR[a]: Not Required

Table 4. Other acceptance and reference tests and operational tests for non-imaging *in vivo* counting systems (ABNT IEC/TR 61948-1:2018) [7].

Non-imaging Intraoperative Gamma Probe	
QC test	**Acceptance Limits / Tolerance Criteria**
Background[a]	NR[a]
Energy Calibration[a]	NR[a]
Sensitivity Constancy[a]	NR[a]
Energy calibration linearity[b]	NR[a]
Constancy of energy resolution[b]	NR[a]

a: Acceptance and reference tests
b: Operational check tests/CQ
NR[a]: Not Required

All acceptance control and quality control tests identified in tables 2, 3 and 4 are not considered in the Brazilian nuclear medicine regulators standards (CNEN and ANVISA). It is noteworthy that although all these tests are not mandatory by these regulators, their performance is important to verify the physical conditions and the clinical performance of these instruments.

3.2 Activity Meter or Dose Calibrator

The main instrument of nuclear medicine is the activity meter since it measures the activity to be administered to the diagnostic or therapy patient, which is the primary quantity to be guaranteed.

The activity meter (dose calibrator) performance check was performed comparing Brazilian standards CNEN NN 3.05 [3], ANVISA RDC 38 [4] and ABNT NBR/IEC-61303:2014 [8] with international recommendations from AAPM Report No. 181 [12] and, IAEA TECDOC 602 [11].

In table 5, the agreement of the performance acceptance limit for the repeatability test between Brazilian standards and international recommendations can be identified. This agreement was also identified for “background (BG) radiation, accuracy and precision” tests.

While Brazilian standard does not specify which conditions/methods and tolerance limits could be considered to improve test performance analysis, international recommendations AAPM Report No. 181 [12] and IAEA TECDOC 602 [11] describe a more concise methodology for conducting

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quality control tests. In addition to describing the test proposal, the step-by-step procedure, the observations to be considered, the interpretation of the results, the acceptability limits, which is a fundamental parameter to guide the operator after performing the quality control test and sets out remarks for report completion.

The document ABNT NBR/IEC 61303:2014 [8] does not describe the acceptability limits for any test described in its standard.

Table 5. Performance limits or tolerance criteria for Activity Meter (Dose Calibrator) [3, 4, 7, 11, 12].

	Brazilian Standards			**International Recommendations**	
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61303**	**AAPM Report No. 181**	**IAEA TECDOC 602**
Repeatability test	σ ± 5%	σ ± 5%	NR[a]	< ±1% of the average measured activity For secondary standard and reference radionuclide calibrators < ± 0.5%.	σ ± 5%
Zero Adjustment Test	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Background Test	σ ± 20%	σ ± 20%	NR[a]	NR[a]	≤ 20%
High Voltage Test	σ ± 1%	σ ± 1%	NR[a]	NR[a]	NR[a]

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Accuracy Test	σ ± 10%	σ ± 10%	NR[a]	Long-lived standards and the two traceable reference sources (± 5%) of the decay-corrected initial values. Secondary standard radionuclide calibrators and reference radionuclide calibrators (± 2%).	σ ± 10%
CQ Test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61303**	**AAPM Report No. 181**	**IAEA TECDOC 602**
Precision Test	σ ± 5%	σ ± 5%	NR[a]	(± 1%) of the average activity measured. For secondary standard radionuclide calibrators and reference radionuclide calibrators (± 0.5%).	σ ± 5%
Linearity Test	σ ± 10%	σ ± 10%	< 1% and <5% of the observed value must be found and recorded.	(± 5%) of the expected values. For secondary standard and reference radionuclide calibrators, linearity using the decaying source method (± 2%). Shield method, linearity using the decaying source method (± 5%).	σ ± 10% (Under conditions of saturation effects, it can reach σ ± 25%, but the measurements must be corrected).

Geometry Test	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]

NR[a]: Not required
σ: standard deviation (**sigma**)

AAPM document Report No. 181 [12] stablished a test named “Equivalence Suppliers” where it is recommended that medical facilities compare their trials with the essay provided by radiopharmaceutical providers and determines the performance limits, being considered differences greater than ±10% should be investigated for cause. When initially establishing equivalence, assay differences should be less that ± 5% and, if greater, the reason for the differences should be determined and corrected.

3.3 Gamma Camera – Single Photon Emission Computed Tomography (SPECT)

In Brazil, according to DATASUS, there are 82 Positron Emission Tomographs, of which 79 are in use, and 768 Scintillation Cameras, 739 are in operation [2].

Table 6 shows the comparison of performance/tolerance limits for SPECT scintillation cameras. It was identified that CNEN and ANVISA do not establish an acceptable limit for the QC evaluation in their standards. The ABNT standard also does not address performance limits for the most characteristic, only for the linearity test [3, 4, 9].

International recommendations from IAEA documents, TECDOC 602 [11] and HHS No. 6 [18], agreed on their performance evaluation. AAPM Report No. 177 [19] address the tolerance/performance limits for the following tests: physical inspection that establishes light conditions for image monitors, full and differential uniformity for high counting density, instrumental uniformity for other radionuclides other than Technitium-99m (^{99m}Tc), intrinsic spatial resolution and linearity, energy resolution, planar or tomographic sensitivity, maximum count rate, full-body scan speed, full field uniformity, and extrinsic system differential if the equipment has this function for all collimators in SPECT camera performance, SPECT/CT Co-registration). NEMA NU 1-2007 [14] had already addressed the tolerance limit for the maximum count rate test only. Many of the tolerance limits stablished in AAPM Report No. 177 [19] are not in line with others international recommendations and are not required by other documents.

Once again we can identify that national documents, although requiring the same QC tests mentioned in international recommendations, do not establish an acceptance/tolerance limit to evaluate the quality control test to be performed, does not define a methodology or conditions to

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conduct and evaluate these tests, nor do they cite a reference document that may serve as a basis for the practitioner who will use these documents.

In Table 6 the performance limits for scintigraphy cameras are presented. Brazilian standards do not describe the methodology for quality control, do not set acceptance limits or performance criteria, nor do they refer to international recommendations that may assist the operator in performing equipment performance testing. From the analyzed international recommendations the documents IAEA HHS nº 6 [18] and AIEA TECDOC 602 [11] present some conformities in their acceptance limits, besides describing the methodology of the execution of the quality control tests presenting the proposal of the tests, the materials to be used, every step-by-step procedure, consideration of data analysis, observations to consider, method of interpretation of results, and conclusion of the quality control test report.

Table 6. Performance limits or tolerance criteria for quality control of SPECT [3, 4, 9, 11, 14, 18, 19].

SPECT							
	Brazilian Standards			International Recommendations			
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61675-2**	**AIEA TECDOC 602**	**AIEA HHS No. 6**	**AAPM Report No. 177**	**NEMA NU 1-2007**
Visual inspection of system physical integrity	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	Monitors: display white (maximum luminance) >120cd/m^2, minimum luminance for black <2cd/m^2, and luminance nonuniformity <20%. Rooms with softcopy monitors (20–40lux).	NR[a]
Intrinsic or extrinsic uniformity, full field and differential for low counting density	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Centering and width of the energetic window for each radionuclide	NR[a]	NR[a]	NR[a]	$\sigma \pm 10\%$ require investigation.	NR[a]	NR[a]	NR[a]
Background radiation from examination room	NR[a]	NR[a]	NR[a]	Count rate ≤20% of reference value	Count rate ≤ 20% of reference value	NR[a]	NRA
Intrinsic integral and differential field uniformity if the equipment has this function for high counting	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	Integral Uniformity (IU) for 5 million count floods over the UFOV[b] should be <5%.	NR[a]

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density							
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61675-2**	**AIEA TECDOC 602**	**IAEA HHS No. 6**	**AAPM Report No. 177**	**NEMA NU 1-2007**
Intrinsic uniformity for nuclides other than 99mTc	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	IU for 5.10^6counts floods over the UFOV[b] should <5%.	NR[a]
Intrinsic uniformity with asymmetric energy windows	NR[a]	NR[a]	NR[a]	NR[a]	Intrinsic flood field uniformity at a 15% PHA[b] window. The uniformity may degrade with a 10% PHA[b] window in a properly functioning camera.	NR[a]	NR[a]
Intrinsic spatial resolution and linearity	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	Intrinsic spatial resolution is 3–4mm FWHM[e] for ^{99m}Tc, should be able to resolve 2.5mm bars. Any nonlinearity <1mm.	NR[a]
Extrinsic planar spatial resolution and linearity	NR[a]	NR[a]	NR[a]	FWHM[e] ≤20% of manufacturer's worst-case value for the collimator in question.	FWHM[e] ≤20% of manufacturer's worst-case value for the collimator in question.	NR[a]	NR[a]

Energy resolution	NR[a]	NR[a]	NR[a]	FWHM[d] (σ ±9%)	NR[a]	FWHM[e] of a NaI(Tl)-crystal Anger camera for 99^{m}Tc is 9–10%.	NR[a]
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61675-2**	**AIEA TECDOC 602**	**IAEA HHS No. 6**	**AAPM Report No. 177**	**NEMA NU 1-2007**
SPECT Camera Rotation Center (COR)	NR[a]	NR[a]	NR[a]	(COR) offset < 2mm. The COR offset estimated at the centre and for the edges of the field (2mm) of each other. For multiple head systems, Y=0, as well as the Y gain, should be the same for both heads.	(COR) offset < 2mm. The COR offset estimated at the centre and for the edges of the field (2mm) of each other. For multiple head systems, Y=0, as well as the Y gain, should be the same for both heads.	NR[a]	NR[a]
Spatial resolution for multienergy sources, if applicable	NR[a]	NR[a]	NR[a]	FWHM[e] ≤ 20%.	FWHM[e] ≤ 20%.	NR[a]	NR[a]

Spatial co-registration of images for multienergy emission sources, if applicable	NR[a]	NR[a]	NR[a]	Method 1: An absolute position difference between two PHA[c] windows should never >1–2mm. Method 2: (X,Y ≥10%) corrective action should be initiated. At routine testing by method 2, displacement should be <20% from the reference value.	Method 1: An absolute position difference between two PHA[c] windows should never >1–2 mm. Method 2: (X,Y ≥10%) corrective action should be initiated. At routine testing by method 2, displacement should be <20% from the reference value.	NR[a]	NR[a]
CQ Test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61675-2**	**AIEA TECDOC 602**	**IAEA HHS No. 6**	**AAPM Report No. 177**	**NEMA NU 1-2007**
Planar or Tomographic Sensitivity	NR[a]	NR[a]	NR[a]	Sensitivity value ≤10%.	Sensitivity value ≤10%.	± 5%.	NR[a]
Maximum Count Rate (MCR)	NR[a]	NR[a]	NR[a]	At acceptance testing (MCR ≤10%). At routine testing (MCR ±20%).	At acceptance testing (MCR ≤10%). At routine testing (MCR ±20%).	Expected intrinsic MCR typically <150,000 cps for an Anger camera.	Observed count rate should be not > 20%.
Checking the hole angulation defects of all collimators	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]

Equipment examination table speed at full body scan	NR[a]	NR[a]	$\sigma > (\pm 4.\sigma)$ shall be declared.	NR[a]	< 5%	Measured spatial: +10% of the spatial resolution. Whole-Body Scanning Uniformity: Coefficient of variation< 2%. System sensitivity: ±5%.	NR[a]
Integral field uniformity and extrinsic differential of the system if the equipment has this function for all collimators in use	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	The IU over the UFOV[b] should be <5% for 5.10^6count floods.	NR[a]
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/ NBR/ IEC 61675-2**	**AIEA TECDOC 602**	**IAEA HHS No. 6**	**AAPM Report No. 177**	**NEMA NU 1-2007**
SPECT Camera Overall Performance	NR[a]	NR[a]	NR[a]	± 10%	NR[a]	• Spatial Resolution: 11.1mm rods fully resolved. • Contrast: The 15.9mm sphere is visualized. • Uniformity: No ring artifacts with magnitude greater than the magnitude of the noise, or if ring artifacts are visible in a few	NR[a]

						slices, they should not be considered likely to be clinically significant.	
Pixel Size Test	NR[a]	NR[a]	NR[a]	(X, Y < 5%)	(X, Y < 5%)	NR[a]	
Verification of the operation of the computer system and peripherals	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Checking computer time in dynamic studies	NR[a]	NR[a]	NR[a]	Time lost between frames should not > 5% of the shortest frame time and time lost per frame should not be > 5% either.	Time lost between frames should not be > 5% of the shortest frame time and time lost per frame should not be > 5% either.	NR[a]	NR[a]
Verification of acquisition synchronized with physiological signals.	NR[a]	NR[a]	NR[a]	(3.σ) of the random count error (the square root of the mean count) in the first three quarters of the time-activity curve.	(3.σ) of the random count error (the square root of the mean count) in the first three quarters of the time-activity curve.	NR[a]	NR[a]
QC test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/ NBR/ IEC 61675-2**	**AIEA TECDOC 602**	**IAEA HHS No. 6**	**AAPM Report No. 177**	**NEMA NU 1-2007**
Detection system shielding check	NR[a]	NR[a]	NR[a]	Measured count should not > BG[c] count by (3.σ).	NR[a]	NR[a]	NR[a]
SPECT/CT Co-Registration	NR[a]	NR[a]	NR[a]	Measured count should not > BG[c] count by (3.σ).	NR[a]	σ < 5mm.	NR[a]

NR[a]: Not Required
σ: standard deviation (sigma)

UFOV[b]: Useful Field of View
PHA[c]: pulse-height analyzer
BG[d]: Backgroud radiation
FWHM[e] : Full Width at Half-Maximum

In Table 6 above, the performance limits for scintigraphic cameras are presented. Brazilian standards do not describe the methodology for quality control, do not set acceptance limits or performance criteria, nor do they refer to international recommendations that may assist the operator in performing equipment performance testing. From the analyzed international recommendations, the documents IAEA HHS nº 6 [18] and IAEA TECDOC 602 [11], present some conformities in their acceptance limits, besides describing the methodology of the execution of the quality control tests, presenting the proposal of the tests, the materials to be used, every step-by-step procedure, consideration of data analysis, observations to consider, method of interpretation of results, and conclusion of the quality control test report.

3.3.1 Positron Emission Tomography (PET)

In table 7, only IAEA document HHS No. 1 [17] presents some acceptance limits for quality control tests. Although PET technology is recent, this technology only arrived in Brazil in 1998 [20]. Therefore, from NEMA NU 2-2007 [15], which is the international recommendation used in the most recent Brazilian standard, CNEN NN 3.05 [3], in QC acceptance limits were addressed to this equipment. Also, the acceptability limitation approach for PET quality control testing in this comparison is identified only in IAEA document, HHS No. 1 [17]. However, we can look at the time lag between technology development and the development of a recommendation addressing such concepts of limiting the acceptability of quality control testing. This document presents acceptability limits for some quality control tests; besides, it also presents the test purpose to be performed, recommended frequency, materials to be used, defines the procedure, guides data analysis and indicates corrective actions if any QC tests present different performance than the one proposed by the manual.

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Table 7. Performance limits or tolerance criteria for quality control of Positron Emission Tomography [3, 4, 10, 15, 17].

	Brazilian Standards			International Recommendations	
CQ Test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61675-1**	**IAEA HHS nº1**	**NEMA NU 2-2007**
Visual inspection and physical integrity	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Detector stability system check	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Time resolution in coincidence marking in flight time-of-flight system (TOF)	NR[a]	NR[a]	NR[a]	$TR^{b}_{measured} < 1.05 TR^{b}_{expected}$	NR[a]
Uniformity	NR[a]	NR[a]	NR[a]	$\%NU^{c}_{measured} < 1.05 \%NU^{c}_{reference}$	NR[a]
Normalization	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
System Calibration Check	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
PET/CT co-registration	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Radioactive Concentration Calibration or Volume Sensitivity Sensing Check	NR[a]	NR[a]	NR[a]	$\sigma < \pm 5\%$	NR[a]
Energy resolution	NR[a]	NR[a]	NR[a]	$ER^{d}_{measured} < 1.05 ER^{d}_{expected}$	NR[a]
Spatial resolution in transverse and axial directions	NR[a]	NR[a]	NR[a]	The expected ratio of FWTM[e] to FWHM[f] for a real PET scanner should be approximately in the range 1.8 to 2.0.	NR[a]

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				$FWHM^{f}_{observed} < 1.05 FWHM^{f}_{expected}$	
CQ Test	**CNEN NN 3.05**	**ANVISA RDC 38**	**ABNT/NBR/ IEC 61675-1**	**IAEA HHS nº1**	**NEMA NU 2-2007**
Sensitivity	NR[a]	NR[a]	NR[a]	$S_{tol}{}^{g}{}_{measured} > 0.95 S_{tol}{}^{g}{}_{,expected}$	NR[a]
Scattering fraction	NR[a]	NR[a]	NR[a]	$SF^{h}_{observed} < 1{,}05 SF^{h}_{espected}$	NR[a]
Window width of temporal coincidence	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Slice thickness	NR[a]	NR[a]	NR[a]	± 1mm	NR[a]
Count Rate Performance	NR[a]	NR[a]	NR[a]	$SF^{h}_{observed} < 1{,}05 SF^{h}_{espected}$	NR[a]
True Event Rate	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Random Event Rate	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Overall PET Performance	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Overall PET/CT Performance	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Mechanical Parts of Equipment	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Accuracy in random event corrections	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]
Accuracy of count loss fixes	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]

CQ Test	CNEN NN 3.05	ANVISA RDC 38	ABNT/NBR/ IEC 61675-1	IAEA HHS nº1	NEMA NU 2-2007
Accuracy of scatter corrections	NR[a]	NR[a]	NR[a]	± 5%	NR[a]
Accuracy of attenuation corrections	NR[a]	NR[a]	NR[a]	± 5%	NR[a]
Pixel size	NR[a]	NR[a]	NR[a]	NR[a]	NR[a]

NR[a] : Not Required
TR[b] : Timing Resolution
NU[c] : Non-Uniformity
ER[d] : Energy Resolution
FWTM[e] : Full Width at Tenth-Maximum
FWHM[f] : Full Width at Half-Maximum
S_{tol}[g]: Total Sensitivity
SF[h] : Scattering Fraction

4. CONCLUSIONS

It is concluded that the documents of the agencies responsible for the supervision and regulatory control of the Brazilian NMS, ANVISA and CNEN, are insufficient regarding the QC tests that are essential to verify the operation and guarantee the good performance of these instruments.

The Brazilian standards, although more recent than some international recommendations, still fail as documents that can provide operational support to equipment nuclear medicine quality control. The regulatory standards need reformulation in some specific points, as regards non-imaging equipment since require that only one test must be performed for uptake and radiosurgery probes. ABNT IEC/TR 61948:1 [7] standard describes five more performance evaluation tests for this equipment but does not also define tolerance criteria. The international recommendations [11, 16] make available on average of 15 acceptance/reference and operational routine tests to be performed on these instruments, besides describing the method of accomplishment and performance/tolerance limits.

Regarding Positron Emitting Tomography, only recommendation from IAEA, HHS No. 6 [18], establish acceptance limits while no Brazilian standard or technical document do it. For SPECT systems, national standards do not require/set performance limits for equipment quality control testing.

International recommendations used in these comparisons, the IAEA TECDOC 602 [11], IAEA HHS No. 6 [18] and the AAPM Report No. 177 [19], were the international documents that indicated acceptance/tolerance values for the QC tests described here.

It is also possible to observe that standards of Brazilian regulators, regarding the execution of QC tests, there is no methodology or conditions for carrying out these quality control tests, which is a condition of importance for the guidance of operators. At this point, the international recommendations are more complete, as they had better guide the execution and the conditions to carry out and evaluate the tests, in addition to providing some tolerance limits.

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In fact, Brazilian standards do not provide acceptance limits for performance evaluation of quality control tests. Most international recommendations indicate acceptance/tolerance limit values to evaluate the quality control test performed.

Acceptance limits or tolerance criteria are usually set by the equipment manufacturer, but the user should set their reference values, tolerances, and action levels, i.e. to trigger the decision to make a maintenance call or whether the equipment must be kept out of operation due to a lack of reliability in its performance. It is important that the documents from the Brazilian regulators be reviewed concerning what is required of quality control testing, performance limits and methodology to perform, to better guide operators and ensure better reliability of their quality control tests.

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