PNRI Administrative Order No. 01
Series of 2022

CRITERIA FOR THE ACCEPTABILITY OF IMAGING EQUIPMENT USED IN NUCLEAR MEDICINE

WHEREAS, the Philippine Nuclear Research Institute, hereinafter referred to as PNRI, is mandated by Republic Act No. 5207: "Atomic Energy Regulatory and Liability Act of 1968", as amended, to establish and issue regulations and orders with respect to atomic energy facilities and materials for the protection of the health and safety of the workers and of the general public, and for this purpose the regulations are codified in the Code of PNRI Regulations (CPR);

WHEREAS, CPR Part 3, Standards For Protection Against Radiation, Rev. 02 prescribes the requirements on radiation protection and safety based on the three radiation protection principles - justification, optimization, dose limitation, that shall be complied by all holders of PNRI license;

WHEREAS, CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material", Rev. 2 prescribes the requirements and provisions for the issuance of license authorizing the medical use of unsealed radioactive material in diagnosis, therapy, in-vitro clinical and laboratory studies, and in medical research;

WHEREAS, Section 38, "Quality Assurance for Medical Exposure" of CPR Part 3 and Section 31, "Quality Assurance (QA) Program of Nuclear Medicine Equipment" of CPR Part 13 provide for the establishment of a comprehensive quality assurance program for all nuclear medicine imaging equipment, including measurements and verification of physical parameters, and to implement corrective actions if measured values are outside established tolerance limits;

WHEREAS, as a requirement to licensing, all nuclear medicine equipment used in medical exposures are required to demonstrate compliance to technical standards for its acceptability, at the time of commissioning (acceptance testing), periodically thereafter (performance testing), after any major repair, and after modification or installation of new software, as applicable;

WHEREAS, to fulfill its statutory obligations as a competent authority under the Act, as amended, the PNRI shall adopt specific criteria of acceptability for equipment safety and performance in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service until it is restored to satisfactory performance;

WHEREAS, the acceptability criteria is expressed as tolerance limits which indicates the minimum acceptable performance in respect of the parameters identified for each of the equipment and which, when exceeded, would require immediate suspension of the equipment from clinical use and investigation of the cause of the unsatisfactory performance;

WHEREFORE, pursuant to the powers vested on PNRI under Section 4 of Republic Act No. 5207, as amended, and Section 16 – a of Republic Act No. 2067, as amended, the Philippine Nuclear Research Institute hereby prescribes the criteria for acceptability of all imaging equipment used in nuclear medicine:

Section I. Requirements for Acceptance and Performance Testing.

a. All nuclear medicine imaging equipment shall be tested upon installation and upon replacement/repair of a major component, and shall be monitored at least annually by the authorized Medical Physicist or a PNRI-licensed service provider to verify that the criteria for acceptability set forth in this Order are being met.

b. The authorized Medical Physicist shall prepare and sign a written report of the findings of acceptance testing and performance evaluation of the equipment.

c. When the performance of the equipment falls outside the tolerance limits, the equipment shall be immediately suspended from clinical use until it is restored to satisfactory performance. The licensee shall ensure that corrective actions are completed in a timely manner consistent with the importance of any adverse findings.

d. The authorized Medical Physicist shall verify and confirm that the equipment is performing in a safe and acceptable manner after the required service is performed.

e. The licensee shall maintain a record of the performance tests, maintenance carried out and a record of failures with details of their repair, for a period specified in the regulations.

Section II. Acceptability Criteria

a. Gamma Camera Systems

	Test	Purpose of Test	Tolerance Limits	Reference*
1	Physical Inspection	To inspect the physical condition of the gamma camera system, the integrity of its shielding, and safety and interlocks.	No shielding damage; no leakage	(IAEA, 2009a)

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2	Computer Monitor Inspection	To evaluate the performance of monitors on computer workstations that are directly associated with the gamma camera system and used for image processing and image interpretation	> 120 cd/m^2 maximum luminance < 2 cd/m^2 minimum luminance < 20% luminance nonuniformity	(AAPM, 2019a)
3	Flood Field Uniformity	To measure the sensitivity variation over the gamma camera UFOV (Useful Field of View) by uniformly flooding the detector crystal with gamma radiation	< 5.0%	(AAPM, 2019a)
4	Intrinsic Spatial Resolution	To test the intrinsic spatial resolution of a gamma camera in terms of the FWHM of its line spread function	< 4 mm FWHM	(AAPM, 2019a)
5	Intrinsic Spatial Linearity	To measure the spatial linearity of the gamma camera detector without the influence of a collimator	< 1 mm	(AAPM, 2019a)
6	Extrinsic Spatial Resolution	To measure the overall spatial resolution of the gamma camera with an installed collimator	≤ 8 mm FWHM	(AAPM, 2019a)
7	Extrinsic Planar Sensitivity	To test the count rate response of a gamma camera to a radionuclide source of known radioactivity	< 5.0% difference for each detector	(AAPM, 2019a)
8	Energy Resolution	To measure the energy resolution of the gamma camera detector by measuring the FWHM of an energy peak expressed as a percentage of the energy peak	< 11% FWHM	(AAPM, 2019a)

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9	Intrinsic Count Rate Performance	To test the intrinsic count rate performance of a gamma camera in terms of its response to an increasing flux of incident gamma radiation	>150,000 cps	(AAPM, 2019a)
10	Multiple Window Spatial Registration	To test that the images acquired at different photon energies superimpose when imaged simultaneously, in an additive or subtractive mode	≤ 2 mm	(IAEA, 2009a)
11	Whole-body Scan Spatial Resolution in air	To test spatial resolution both parallel and perpendicular to the direction of motion	≤ 10% FWHM	(IAEA, 2009a)

***REFERENCE STANDARDS:**

AAPM (2019a) THE REPORT OF AAPM TASK GROUP 177: Acceptance Testing and Annual Physics Survey Recommendations for Gamma Camera, SPECT, and SPECT/CT Systems, Virginia (2019).

IAEA (2009a) International Atomic Energy Agency. Human Health Series No. 6; Quality Assurance for SPECT systems. Vienna (2009).

b. Single-photon Emission Computed Tomography (SPECT), including SPECT/CT Systems *(The basic tests for Planar Gamma Camera systems shall be performed on each detector head used for SPECT before commencing with the tests specific for SPECT.)*

	Test	Purpose of Test	Tolerance Limits	Reference*
1	Physical and Mechanical Inspection of the SPECT System	To check the mechanical performance of the system and its capability to rotate the gamma camera	Acceptable mechanical performance	(IAEA, 2009a)
2	Absolute Pixel Size	To determine the absolute pixel size in the matrix used for tomographic reconstruction	Difference between X and Y values < 5%	(IAEA, 2009a)
3	Tomographic Uniformity	To test the tomographic uniformity of a rotating gamma camera SPECT system	≤ 10%	(IAEA, 2009a)

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4	Tomographic Resolution in Air	To measure the tomographic resolution of the system in air and to ensure that the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction	FWHM ≤ 10%	(IAEA, 2009a)
5	Tomographic Resolution with Scatter	To check the tomographic resolution of the system in clinical conditions, with a radius of rotation that is realistic and with scatter present	< 5%	(IAEA, 2009a)
6	Centre of Rotation Offset and Alignment of Axes	To test the centre of rotation offset, alignment of the camera Y axis and head tilt with respect to the axis of rotation	Offset ≤ 2 mm	(IAEA, 2009a)
7	Slice Thickness at the Center of the Field of View	To test the thickness of a tomographic slice at the centre of the field of view	≤ 10% of tomographic resolution in air	(IAEA, 2009a)
8	Variations of Uniformity and Sensitivity with Angle	To determine the variations in system sensitivity as a function of angular position of the detector	< ±1% of the mean value	(IAEA, 2009a)
9	SPECT/CT Image Quality	To test the overall SPECT/CT image quality	Spatial Resolution: 11.1 mm rods fully resolved. Contrast: The 15.9 mm sphere is visualized. Uniformity: ring artifacts NOT clinically significant	(AAPM, 2019a)
10	SPECT/CT Spatial Registration	To measure the accuracy of the spatial registration (or alignment) of the field-ofview between the reconstructed SPECT and CT images	Mean deviation ≤ 2 mm	(AAPM, 2019a)

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IAEA (2009a) International Atomic Energy Agency. Human Health Series No. 6; Quality Assurance for SPECT systems. Vienna (2009).

c. Positron Emission Tomography (PET), including PET/CT Systems

	Test	Purpose of Test	Tolerance Limits	Reference*
1	Spatial Resolution	To measure the tomographic spatial resolution of the system in air and to ensure that spatial resolution is not degraded by either the tomographic acquisition or the reconstruction process	FWHM < ±5%	(IAEA, 2009b) (AAPM, 2019b)
2	Sensitivity	To determine the rate of detected true coincidence events per unit of radioactivity concentration for a standard source configuration	< ±5%	(IAEA, 2009b) (AAPM, 2019b)
3	Count Rate Performance and Accuracy of Corrections Evaluations	To evaluate the count losses of the system under varying amounts of radioactivity present in the FOV of the PET scanner	< ±5% 0.90–1.10	(AAPM, 2019b)
4	Energy Resolution	Allows an assessment of proper photomultiplier calibration and ensures that the efficiency of light collection is within the specifications	FWHM < 5%	(IAEA, 2009b)
5	Image Uniformity	To provide a measure of the deviation in the activity concentration within a slice, as well as across slices of a uniform phantom	Maximum Absolute Value ≤ 5%	(AAPM, 2019b)
6	Image Quality and Accuracy of Attenuation,	To produce images simulating those obtained in a total body imaging study	< 5%	(IAEA, 2009b)

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	and Scatter Correction and Quantitation	involving both hot and cold lesions		
7	Coincidence Timing Resolution for TOF PET	To determine the capability of the system to estimate the difference in time of arrival of the two coincidence photons, and hence obtain information about the likely location of the annihilation along the LOR	< 5%	(IAEA, 2009b)
8	Accuracy of PET/CT image registration	To assess qualitatively the accuracy of the registrationof the images obtained with the PET and CT scanners	≤ 1 PET voxel	(IAEA, 2009b)

***REFERENCE STANDARDS:**

AAPM (2019b) THE REPORT OF AAPM TASK GROUP 126: PET/CT Acceptance Testing and Quality Assurance, Virginia (2019).

IAEA (2009b) International Atomic Energy Agency. Human Health Series No. 1: Quality Assurance for PET and PET/CT Systems. Vienna (2009).

Section III. Effectivity.

This Order shall take effect fifteen (15) calendar days following its publication in the Official Gazette or in a newspaper of general circulation and shall be enforced until revoked in writing.

APPROVED:

CARLO A. ARCILLA, Ph.D.
Director, PNRI

Date: 27 May 2022

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