



AUSTRALIAN AND NEW ZEALAND SOCIETY OF NUCLEAR MEDICINE INC. (Incorporated in NSW)

Technical Standards Committee

REQUIREMENTS FOR PET ACCREDITATION **(Instrumentation & Radiation Safety)** **3rd Edition (2017) V1.0**

1. Preamble

Positron Emission Tomography (PET) is a nuclear medicine imaging modality that utilises positron emitting radionuclides. PET has well-established applications in oncology and increasingly in a growing range of non-oncologic applications. PET cameras can be either stand-alone single modality devices or hybrid multi-modality systems such as combined PET/CT or PET/MRI.

Requirements for quality assurance in PET, being a quantitative imaging tool, are exacting and for this reason the technical validation of the PET scanner and that of associated equipment requires the active involvement of credentialed staff. The ANZSNM recognises that the geography of our countries combined with the relatively small, highly skilled workforce may present challenges in terms of onsite involvement of qualified staff at all levels. For this reason *active supervision*¹ of aspects of the programme may be performed remotely, not necessarily requiring the on-site attendance of all individuals involved. However, the responsibility associated with the tasks required must still rest with appropriately credentialed individuals.

The purpose of this document is to specify minimum technical requirements for the PET camera (or the PET component of a combined multimodality system) and associated instrumentation to be used in clinical imaging. This document should be regarded by all external organisations as the Society's official standard for acceptability of PET cameras and facilities for clinical use. Note that these technical requirements are not intended to apply to research installations. Further information of PET facility accreditation can be obtained from the AANMS [1].

It is intended to revise this document in no greater than 5 years' time (2022).

2. Requirements for PET Accreditation

- 2.1. A dedicated PET camera (or PET/CT or PET/MRI) with characteristics and performance that meets the criteria in this document;
- 2.2. A dose calibrator that is designed to measure PET radionuclides;
- 2.3. Suitable facilities designed to minimise the radiation exposure of the staff to nationally accepted standards;
- 2.4. A Quality Assurance (QA) plan and calibration schedule for all equipment used in the PET imaging procedure (*i.e.*, PET camera, CT or MRI scanner, dose calibrator) with appropriate record-keeping that is available for inspection at any time by the relevant accreditation authority. The QA plan for

¹ *Active supervision* by a credentialed nuclear medicine physicist can be direct supervision (meaning being present in person or personally performing) or consultative supervision (meaning supervision of other suitably trained individuals involved in the QA programme).

the PET camera or the PET component of a hybrid system shall be under the active supervision of a credentialed nuclear medicine physicist²;

- 2.5. A documented radiation safety programme actively supervised by a designated Radiation Safety Officer³ (RSO) [2] that includes:
- personal monitoring devices, including finger dose monitoring, for all staff involved in the administration of the radiopharmaceutical and subsequent patient handling;
 - adequate record-keeping including staff radiation doses and any adverse incidents;
 - suitable shielding for all personnel during dose preparation, the patient uptake period, and scanning;
 - patient radiation safety protocols and diagnostic reference levels for all examinations using ionising radiation which are to be carried out.

3. Instrumentation Performance Standards

Unless otherwise specified, a guide to the methods used in the assessment of the instrumentation and facilities can be found in the following documents:

- 3.1 PET: Daube-Witherspoon, M. *et al.* PET Performance Measurements Using the NEMA NU 2-2001 Standard. J Nucl Med 43, 1398–1409 (2002) [3];
- 3.2 Dose Calibrator: *The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine*. AAPM Task Group 181 Report 2012 [4];
- 3.3 Radiation Shielding: *PET and PET/CT Shielding Requirements*. AAPM Task Group 108 Report 2006 [5].

Some of the specialised phantoms for the PET NEMA testing procedures have been purchased by the Society and are available for members to borrow. Details can be found on the ANZSNM website (www.anzsnm.org.au).

4. Performance Requirements for Acceptable Clinical Standards

- 4.1 PET: The parameters to be measured and their corresponding acceptable values are:

Parameter	Specification
Transaxial resolution at 1 cm radius from centre of field-of-view	≤ 5.5 mm
Transaxial (tangential) resolution at 10 cm radius from centre of field-of-view	≤ 6.5 mm
Axial resolution at 1 cm radius from centre of field-of-view	≤ 6.5 mm
Axial resolution at 10 cm radius from centre of field-of-view	≤ 7.0 mm
System sensitivity in 3D mode	≥ 4.5 cps/kBq
Noise equivalent count rate (NEC) at 10 kBq.mL ⁻¹	≥ 60 kcps
Maximum count rate error over the central 80% of axial FOV at or below NEC _{peak}	≤ 10%

Table 1. Minimum performance parameters for the PET scanner in an ANZSNM accredited PET facility. All parameters are allowed to have up to 10% deviation in any one measurement.

² A credentialed nuclear medicine physicist is a person who has satisfied the requirements for registration as a qualified Medical Physics Specialist in Nuclear Medicine Physics by the ACPSEM or has been recognised by ACPSEM as qualified to undertake PET Acceptance Testing and Quality Control. The directory of qualified Medical Physics Specialists can be found on the ACPSEM speciality register (www.acpsem.org.au).

³ No nationally recognised standard defining a *Radiation Safety Officer* exists in Australia. For guidance, an example of the technical and scientific skills of a person considered suitable to fulfil the role of an RSO can be found in [2].

4.2 **Dose Calibrator:** The dose calibrator must have a demonstrated accuracy for the PET radionuclides used of better than $\pm 5\%$. Appropriate records must be available to demonstrate the on-going stability of the calibrator.

5. Acceptance and Compliance Testing

The initial acceptance testing of a PET scanner should be directly supervised⁴ by a credentialed nuclear medicine physicist. During this initial acceptance testing the performance of the PET scanner shall be assessed against the manufacturer's published specifications (*e.g.*, NEMA) and also against the performance requirements contained in this document. The nuclear medicine physicist directly supervising the initial acceptance testing shall be independent of the PET scanner manufacturer. The nuclear medicine physicist should also be involved in establishing an appropriate ongoing regular QA programme for the PET scanner. In the usual course of events, the nuclear medicine physicist will also provide subsequent ongoing consultative supervision (as under **6. Regular Quality Control...**). Where compliance testing is required of the PET scanner subsequent to initial acceptance testing (*e.g.*, after moving the device or after a major upgrade), the compliance testing shall be actively supervised by a credentialed nuclear medicine physicist. The scope of the compliance testing will be determined by the circumstances necessitating the compliance testing, and will be decided on by the physicist and the PET facility.

6. Regular Quality Control & Maintaining Optimal Performance

The facility must have and should be able to demonstrate a comprehensive quality control program for PET and dose calibrator plus CT or MRI if present plus evidence of the results, including:

6.1 **PET:** (a) daily QC protocol as specified by the manufacturer including definition of parameters and parameter values that indicate QC failure and trigger an unscheduled service. To demonstrate compliance, the facility may be asked to provide QC records for a 3 month period during the most recent 12 months of operation;

(b) a programme of regular calibration of the PET scanner (*e.g.*, SUV, cross-calibration, *etc*) and QC tests required less frequently than daily, as specified by the manufacturer or developed by the facility, with appropriate record keeping. A check on the SUV values produced for ^{18}F must be performed at least annually using a suitable test phantom available at the site with a clinical acquisition and reconstruction protocol. The study should be a multi-bed position acquisition and should be performed after a delay from the calibration (*e.g.*, 60 mins) to closely resemble a clinical patient examination (*i.e.*, incorporating multi-bed normalisation, decay correction, *etc*). The mean SUV calculated over a range of transverse sections for a homogeneously dispersed solution of ^{18}F in a known volume of water should be in the range 0.95 – 1.05 g.ml⁻¹. A suitable test regime is that of the ACR [6]. An example worksheet for checking SUV values is included in the appendix⁵. The image quality and visual uniformity of the test phantom should be verified by the site. The image data should be available for inspection upon request;

(c) If radionuclides other than ^{18}F (*e.g.*, ^{68}Ga) are used clinically, regular SUV checks (Appendix 1b) should be performed as well to verify satisfactory system performance.

6.2 **CT** (if present): (a) daily QC protocol as specified by the manufacturer;

(b) the scanner should be tested on an annual basis to ensure that it complies with local State regulatory requirements as an irradiating device by a qualified independent testing agency, even if

⁴ *Directly supervised* for the purposes of acceptance and compliance testing means direct personal involvement in performance and evaluation of the testing.

⁵ If a site requires further details about performing the procedure please contact the ANZSNM for guidance and advice.

registration of the device is not required. The RANZCR has approved standards of practice for CT scanners [7];

- 6.3 Dose calibrator: (a) daily checks of stability using a long-lived source (*e.g.*, ¹³⁷Cs, ⁶⁰Co) using the settings for all PET radionuclides in routine use;
(b) regular checks of the accuracy of the calibrator for the PET radionuclides used (principally ¹⁸F). An accuracy check against a supplied, calibrated source from a supplier or government organisation using a traceable standard must be performed at least annually⁶;
- 6.4 A program of regular preventative maintenance, as specified by the manufacturer, and which is carried out by engineers experienced in PET, usually the manufacturer's PET service engineers;
- 6.5 The QA programme for the PET instrumentation must be actively supervised by a credentialed nuclear medicine physicist.

7. Radiation Safety

Specific attention must be paid to the design of the facility, shielding and operational procedures to keep radiation exposure as low as reasonably achievable and below regulatory limits. The PET facility must be able to demonstrate:

- 7.1 Adequate shielding and design of the facility to minimise occupational exposure of staff. The facility layout indicating location, type and thickness of shielding shall be available for inspection. The shielding of the scanner room must also comply with State regulatory requirements for CT installation shielding;
- 7.2 Adequate shielding devices (for both the annihilation photons and positrons) and other means implemented to minimise occupational exposure of staff (*e.g.*, special injection procedures, remote operation of scanner, *etc*);
- 7.3 Routine personnel radiation monitoring and strategies to minimise occupational exposure for any individual. To demonstrate compliance, the facility may be asked to provide personnel monitoring records for the most recent 12 months of operation of any staff member;
- 7.4 Protocols and procedures for handling radiation spills in the PET facility;
- 7.5 A nominated RSO with appropriate experience and specialist training in unsealed sources must oversee and advise on the radiation safety program.

8. Abbreviations and Definitions used in the text

AANMS	Australasian Association of Nuclear Medicine Specialists (formerly ANZAPNM)
AAPM	American Association of Physics in Medicine
ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
ACR	American College of Radiology
ANZSNM	Australian and New Zealand Society of Nuclear Medicine (referred to as " <i>the Society</i> ")
IAEA	International Atomic Energy Agency
IEC	International Electro-technical Commission (Laussane, Switzerland)
NEC	Noise Equivalent Count Rate, a measure of data acquisition rate
NEMA	National Electrical Manufacturers' Association (Baltimore, USA)
PET	Positron Emission Tomography
QA	Quality Assurance – the processes by which quality is checked and maintained
QC	Quality Control – the methods used to measure the performance of a device or system
RANZCR	Royal Australian & New Zealand College of Radiologists

⁶ This is consistent with other dose calibrator testing required by ANZSNM.

This document was originally prepared by the PET Working Group of the Technical Standards Committee of the Australian and New Zealand Society of Nuclear Medicine. The PET Working Group comprised Dale Bailey (NSW rep), David Binns (VIC rep), Graeme O'Keefe (Physics SIG rep), Darin O'Keefe (NZ rep) and Alex Pitman (AANMS rep). This version (3rd Ed.) with minor revisions was made by Dale Bailey and Darin O'Keefe in September 2017. Last updated 12 September 2017.

9. References

1. AANMS, *Standards for Accreditation of Nuclear Medicine Practices (Second Edition)*. 2005, Australasian Association of Nuclear Medicine Specialists.
2. EPA NSW, *NSW Radiation Series No.5 - Recommendations for Radiation Safety Officers and Radiation Safety Committees*, in *NSW Radiation Series*. 2003.
3. Daube-Witherspoon, M., et al., *PET Performance Measurements Using the NEMA NU 2-2001 Standard*. *J Nucl Med*, 2002. **43**(10): p. 1398–1409.
4. AAPM, *The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine in Task Group 181 Report*. 2012.
5. AAPM, *PET and PET/CT Shielding Requirements*, in *Task Group 108 Report*. 2006.
6. ACR, *PET Phantom Instructions for Evaluation of PET Image Quality*, in *ACR Nuclear Medicine Accreditation Program*. 2011, American College of Radiology.
7. RANZCR, *Standards of Practice for Diagnostic and Interventional Radiology*. 2009, Royal Australasian College of Radiologists.



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CHECKLIST

Facility: _____

Date: / /

	REQUIREMENT	Reference*	RESPONSE	
1	PET camera – make and model, installation date	2.1		<input type="checkbox"/>
2	Dose calibrator – make and model, installation date	2.2		<input type="checkbox"/>
3	Suitable radiation protection of facilities – design and verification available?	2.3, 7.1, 7.2, 7.3		<input type="checkbox"/>
4	Documented Quality Assurance plan for: <ul style="list-style-type: none"> • PET • CT or MRI as applicable • Dose Calibrator 	2.4		<input type="checkbox"/>
5	Name of certified nuclear medicine physicist & ACPSEM Medical Physics Specialist Registration No.	2.4, 6.5		<input type="checkbox"/>
6	Name of PET Radiation Safety Officer (RSO) with specialised training in unsealed radioactive sources	2.5, 7.5		<input type="checkbox"/>
7	Documented or demonstrable radiation safety programme for: <ul style="list-style-type: none"> • Personal monitoring • Records of monitoring • Radiation protection during dose preparation and administration • Patient radiation safety protocols and DRLs 	2.5		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

8	Evidence of acceptance test measured values for PET performance (indicate any non-compliances with values in Table 1)	4.1		<input type="checkbox"/>
9	Evidence of measured accuracy of dose calibrator – indicate PET radionuclides tested	4.2		<input type="checkbox"/>
10	Evidence of daily QC for PET scanner	6.1(a)		<input type="checkbox"/>
11	Evidence of regular calibration & SUV check for PET	6.1(b)		<input type="checkbox"/>
12	If CT present, evidence of daily QC of CT	6.2(a)		<input type="checkbox"/>
13	If CT present, evidence of annual compliance check	6.2(b)		<input type="checkbox"/>
14	Evidence of daily QC for dose calibrator	6.3(a)		<input type="checkbox"/>
15	Evidence of annual accuracy check of dose calibrator	6.3(b)		<input type="checkbox"/>
16	Programme of preventative maintenance for PET	6.4		<input type="checkbox"/>
17	Protocols for handling radioactive substances including radioactive spill procedure	7.4		<input type="checkbox"/>

*Section referred to in the ANZSNM document *Requirements for PET Accreditation (2nd Ed)*

Name (print): _____

Position with Facility: _____

Name (sign): _____

Date: / /

This form should be completed annually and available for review if requested



APPENDIX 1a: PET DOSE CALIBRATOR & SCANNER CALIBRATION WORKSHEET

Date: / / **Performed by** (your name): _____

PET Facility (hospital or practice and location): _____

Dose Calibrator: _____ **Radionuclide:** _____

DOSE CALIBRATOR ACCURACY CHECK

Supplier's Calibration Data: Total activity: _____ MBq at _____ hrs - (D1)

(if applicable)

Measured Calibration Data: Total activity: _____ MBq at _____ hrs - (D2)

Time difference (t_{diff}): _____ mins

Difference from calibrated value:

$$Diff\% = \frac{D1 - D2 \exp(\lambda \times t_{diff})}{D1} \times 100 ; \quad (D2^*) = D2 \times \exp(\lambda \times t_{diff})$$

=

$$= (D1 - D2^*) / D1 \times 100(\%)$$

= %

Signed: _____

λ values and half lives for common radionuclides

Tracer	Half life (mins)	λ (mins ⁻¹)
¹⁸ F	109.8	0.00633
⁶⁸ Ga	68	0.0102
¹¹ C	20.4	0.0340
^{99m} Tc	361.2	

