Technical Standards Committee PET Accreditation Document

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Background

- Unlike gamma cameras, performance of PET imaging devices can vary by more than order of magnitude depending on technology employed
- Recognised in DoHA report “Report of the Review of Positron Emission Tomography August 2000”

Table 8 Performance parameters for various PET technologies

		Full-ring BGO		Partial-ring BGO	NaI PET	NaI gamma camera
		2D	3D	3D	3D	2.5D
In-plane resolution (mm)	r=1 cm	4.5x4.5	4.5x4.7	5.7x6.0	5.5	5
	r=10 cm	4.5x6.0	4.5x6.0	6.4x6.7	5.8	8
Axial resolution (mm)	r=0 cm	3.9	3.9	6.0	6.0	5
	r=10 cm	4.8	5.3	7.2	6.0	8
Sensitivity (cps/Bq/mL)		5.7	30.4	7.5	12.2	0.26
Scatter fraction (%)		17	37	32	28	16
Peak NEC (kilo-cps)		84	110	27	30	0.9
Activity at peak (kiBq/mL)		130	24.1	14.7	7.0	7.1

cps = counts per second, Bq/mL = becquerels per millilitre

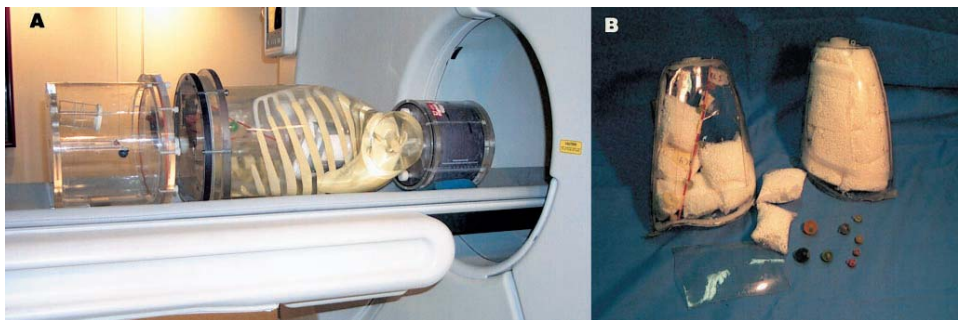
Table 9 Expected noise equivalent count (NEC) for whole body studies

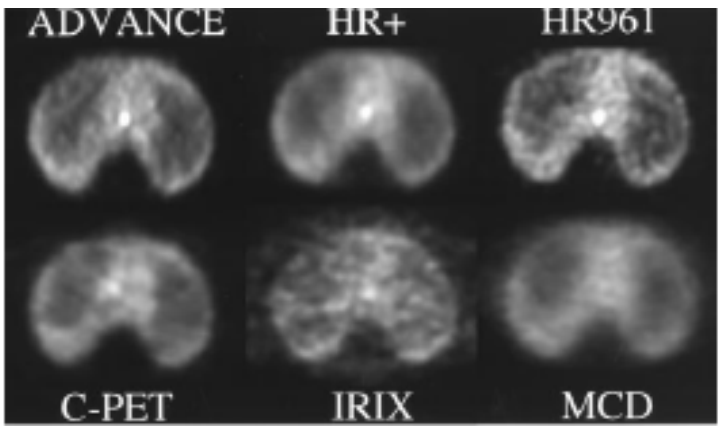
Technology	NEC (kcps)
Current generation BGO (2D)	50–60
BGO systems (2D) installed in Australia (≈10 years old)	20–30
Current generation NaI	10–20
Gamma camera based coincidence systems	0.5–2

BGO = bismuth germanate, kcps = kilocounts per second

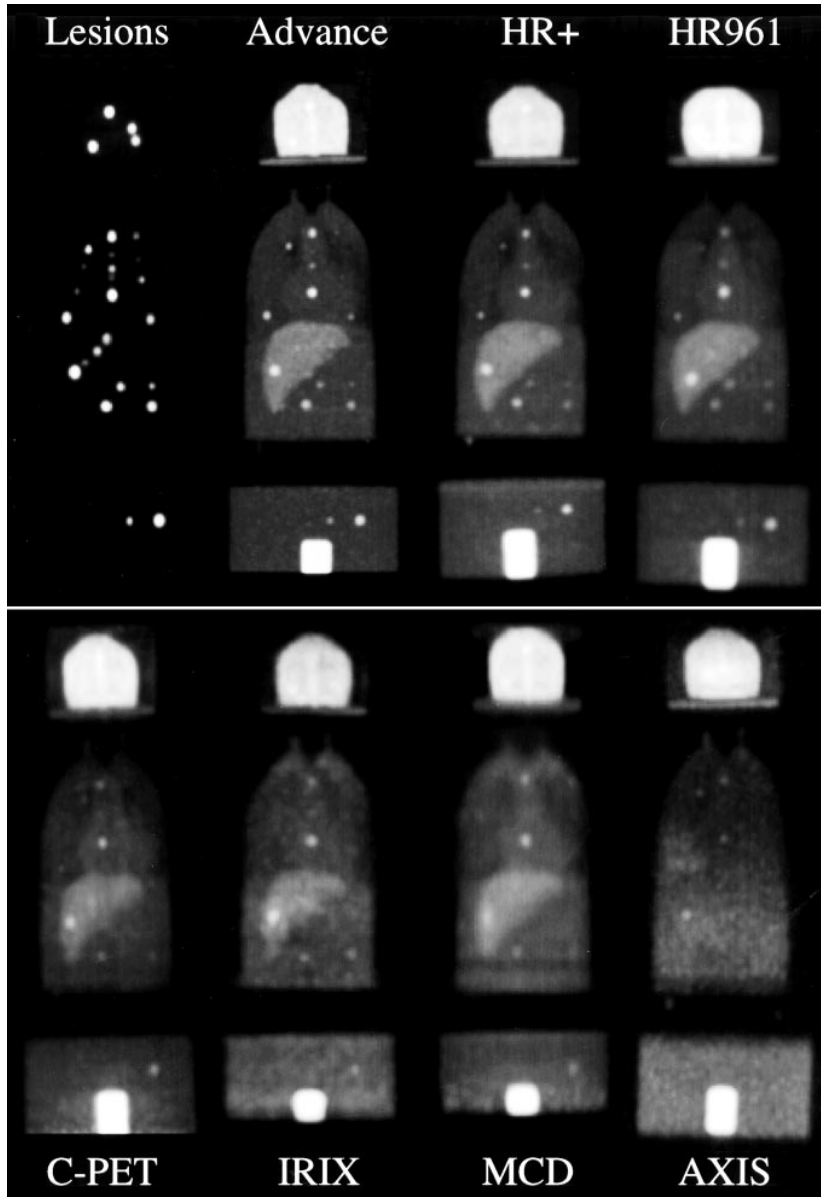
Comparative Evaluation of Lesion Detectability for 6 PET Imaging Platforms Using a Highly Reproducible Whole-Body Phantom with ^{22}Na Lesions and Localization ROC Analysis

Dan J Kadrmas, PhD and Paul E Christian, BSc
J Nucl Med 2002; 43:1545-1554





12 mm lesion, 3:1 contrast ratio



TSC “Interim Recommendations for PET Accreditation (Technical Aspects) – May 2001”

- Instrumentation requirements
  - Dedicated PET scanner (BGO, LSO, NaI(Tl) etc)
  - Meet stipulated performance requirements (draft NEMA NU2-2000 -> NEMA NU2-2001)
- Comprehensive QC program
  - Recommended to be supervised by PET experienced physicist or engineer
- Radiation Safety
  - Shielding
  - Staff protection
  - Radiation protection procedures and protocols
  - Radiation Safety Officer recommended
- Additional Requirements for a Comprehensive PET Facility

TSC 2001 Performance Requirements (Draft NEMA2000)

Parameter	*Specification*
Transverse resolution at 1 cm radius	≤ 6.5 mm
Axial resolution at 1 cm radius	≤ 6.5 mm
Transverse (tangential) resolution at 10 cm radius	≤ 8 mm
Axial resolution at 10 cm radius	≤ 8 mm
System sensitivity	≥ 0.1%
Peak noise equivalent count rate (NEC_{peak})	≥ 20,000 counts/sec
Maximum count rate bias (after dead time correction) at or below NEC_{peak}	≤ 10%
Quantitative error in recovering activity concentration[1]	< 10%

Why Care About the ANZSNM TSC PET Document?

- Referred to and requirement (as recommended by ANZAPNM) in
  - Initial DoHA PET Service Tender RFT 7/0102 (2001)
  - Health Insurance (Positron Emission Tomography) Determination HS/07/05 – 6/12/2005.
    - SPN, NSCLC and refractory epilepsy Medicare item numbers

Revision of Interim Recommendations

- Update drafted by Dale Bailey, Graeme O'Keefe and Steven Meikle in early 2006 for the TSC.
- ANZAPNM reviewed it several times, changes made, concerns addressed. Also feedback and clarification on a number of issues from DoHA.
- Meeting held between ANZAPNM, ANZSNM and TSC on 24th Nov 2006 – consensus reached on a document to be published on ANZSNM website for comment
- Draft published early Dec 2006, with comment period closing on 22 December 2006.
- Modified document and responses to comments forwarded to ANZSNM Federal Committee 26 Jan 2007.
- ANZSNM Federal Committee considered modifications and response to comments at meeting 8 Feb 07 and considered them adequately addressed and recommended adoption of document and informed ANZAPNM accordingly.
- Further concerns raised by ANZAPNM, adoption of document put on hold until addressed by TSC – several iterations. Main concern was mandated physicist requirement and physicist definition.
- Meeting held at the Adelaide Conference between main stake holder (ANZAPNM) and representatives from ANZSNM Federal Committee and chair of TSC to address remaining issues.
- Document adopted by ANZSNM Federal Committee and forwarded to ANZAPNM and DoHA early May 2007.
- Published on ANZSNM website Dec 2007.
- Not yet adopted by DoHA or ANZAPNM …

Adoption Process

- Initial comments from main stake holders (ANZAPNM, DoHA)
- Public comment – opportunity for all stake holders in Nuclear Medicine community to comment (ANZSNM covers all disciplines)
- Comments to be addressed by the TSC to the satisfaction of ANZSNM executive
- Process resulted in improved document
- However, process perhaps too protracted and at times adversarial

The Updated Document

- Still same basic components
  - Instrument performance
  - QC
  - Radiation Safety
- Recommendations in 2001 document now largely mandatory
- Includes CT acceptance and QC requirements
- Phase in period till 1st July, 2008.

Instrumentation

- Scanners classified into 3 generations
  - 1st Generation – early designs pre-1986
  - 2nd Generation – 2D/3D multi-ring and volume imaging scanners based on moderately slow detector scintillation crystals (1986-2000)
  - 3rd Generation – 3D-only multi-ring scanners based on fast scintillation crystals (eg LSO, GSO, LYSO) (2000-present)
- Requirement
  - Dedicated high performance 2nd or 3rd generation PET or PET/CT scanner

Instrument Performance Values

- How determined?
  - Performance of current generation scanners
  - Performance of installed scanners in Australia
  - Performance of scanners which contributed majority of data to the federal data collection

Instrumentation Performance

Parameter	TSC2001	TSC2007
Transverse Resolution at 1 cm radius	≤ 6.5 mm	≤ 6.5 mm
Axial Resolution at 1 cm radius	≤ 6.5 mm	≤ 6.0 mm
Transverse (tangential) resolution at 10 cm radius	≤ 8 mm	≤ 8 mm
Axial resolution at 10 cm	≤ 8 mm	≤ 8 mm
System sensitivity	≥ 0.1%	≥ 4.0 cps/kBq
Peak noise equivalent count rate (NEC_{peak}) *(TSC2007 at activity concentrations of ≤10kBq/ml)*	≥ 20 kcps	≥ 30 kcps
Maximum count rate bias (after dead time correction) at or below NEC_{peak} (*TSC2007 Maximum count rate error over the central 80% of axial FOV (after dead time correction) at or below NEC_{peak}*)	≤ 10%	≤ 10%
Quantitative error in recovering activity concentration	< 10%	----

Instrument Performance Specifications – Comparison with Measured Values

Parameter	TSC2007	Philips Gemini (Allegro)	Siemens Biograph LSO	Philips GXL	GE DSTE	Siemens TrueV 4R
Transverse Resolution at 1 cm radius	≤ 6.5 mm	5.0 mm	6.5 mm	5.4 mm	4.9 mm	4.2 mm
Axial Resolution at 1 cm radius	≤ 6.0 mm	5.2 mm	5.7 mm	5.6 mm	5.4 mm	4.5 mm
Transverse (tangential) resolution at 10 cm radius	≤ 8 mm	5.7 mm	7.5 mm	5.9 mm	5.6 mm	4.7 mm
Axial resolution at 10 cm	≤ 8 mm	5.8 mm	7.1 mm	6.9 mm	5.9 mm	5.8 mm
System sensitivity	≥ 4.0 cps/kBq	4.2 cps/kBq	6.5 cps/kBq	7.5 cps/kBq	8.8 cps/kBq	8.1 cps/kBq
Peak noise equivalent count rate (NEC_{peak}) at activity concentrations of ≤10kBq/ml	≥ 30 kcps	30.5 kcps	50 kcps	69 kcps	60 kcps	109 kcps
Maximum count rate error over the central 80% of axial FOV (after dead time correction) at or below NEC_{peak}	≤ 10%	---	---	8.9%	9.5%	8.0%

Instrumentation - Other

- Dose Calibrator
  - Suitable for measuring PET radioisotopes with settings for PET radioisotopes
  - Daily QC (long term drift, background and zero setting)
  - Accuracy checked during ANZSNM dose calibrator survey
    - No positron emitter activity standard available

Radiation Safety

- Adequate shielding and design of facility to minimise exposure and meet regulatory requirements
- Shielding devices for doses, phantoms, vials etc
- Routine personnel radiation monitoring
- Protocols and procedures for handling radiation spills
- Radiation safety officer with specialists training in unsealed sources must oversee and advise on the radiation safety programme

QC

- Daily QC for PET (and CT, if present)
- If present, CT scanner needs to be compliance tested to comply with regulatory requirements
- Regular scanner calibration (eg SUV, normalisation)
- Regular preventive maintenance

Supervision of QC and Sign off on Performance Tests

- Need to verify that equipment meets manufacturer's and TSC specifications
- Need to ensure that equipment continues to perform optimally, artefact free and is properly calibrated
- Need to be properly documented, supervised and signed off by a qualified person to readily demonstrate compliance
- Uniform standard across PET practices
- Compliance testing, testing certificates by CRE etc quite common for other imaging equipment (eg Radiology).
- Mandatory requirement, rather than recommendation

Sign-off Requirements

- “Measurements on new and existing scanners to demonstrate compliance with accreditation requirements must be conducted by, or supervised by, a *suitably qualified person*”
- “For new scanners, acceptance test results may be used to demonstrate compliance if a *suitably qualified person* supervised and signed off on the acceptance tests.”
- “The results of all acceptance and compliance testing must be signed off by a *suitably qualified person*.”
- “A documented QC and calibration programme for the PET scanner (and CT, if present) as recommended by the manufacturer with suitable records, *actively supervised* by a *suitably qualified person*.”
- “The QC programme must be *actively supervised* by a *suitably qualified person.*”

Definitions

- "*Suitably qualified person*" – a person who is either
  - A qualified nuclear medicine physicist as defined below

OR

  - Has been certified by the ACPSEM Nuclear Medicine Physics Accreditation Panel as suitably qualified to supervise PET QC and PET acceptance testing. Criteria for certification will be fully established by 1st January, 2008.
- "A qualified nuclear medicine physicist" for these purposes is a person who is either:
  - On the ACPSEM's speciality register of Nuclear Medicine Physicists

OR

  - Has been deemed by the ACPSEM to be eligible for ordinary membership of the ACPSEM and who has been practising as either a Nuclear Medicine Physicist for at least the previous 5 years or as a full time PET physicist for at least the previous 2 years
- "*Actively supervised"*
  - Supervised by a *suitable qualified person* who is actively involved in setting up the QC programme, protocol and documentation, reviews the QC results on at least a quarterly basis, reviews the results of scanner calibrations and is available for consultation for issues involving scanner QC, calibration and performance.

Issues

- Why physicists and not other groups eg service engineers?
  - Independence from vendors
  - Expertise, judgement calls and advice
- Sufficient number of physicists and geographical coverage
  - Survey of NucMed physicists numbers and geographical distribution
  - Appropriate, inclusive definition “suitably qualified person”
  - Workforce planning
- Cost
  - Very moderate requirements, little additional cost to overall running cost of PET facility
  - Does not require full time employment of NucMed Physicist by every PET practice!
- “Restricted trade”
  - Definition
  - Legal advice and exemption through ACPSEM
  - Formal advice from DoHA
- Role of ACPSEM
  - Currently the only organisation in Australia and NZ which has mechanisms and structures in place for assessing qualifications of and accrediting medical physicists
  - Document is ANZSNM document, not ACPSEM document!
- Approach to issues
  - Water down requirement
  - Find way of addressing/resolving issues

PET Acceptance and QC Certification

- Draft document considered by ACPSEM Council and Professional Standards Board (PSB)
  - Some minor changes being made before being finalized
- Requires
  - Experience in Nuc Med Physics
  - Practical experience in PET acceptance testing and QC through either
    - Practical experience already obtained

    OR
    - Attendance of approved practical course (2 days)
  - Passing of written (open book) exam

PET Acceptance Test and QC Course

- Syllabus drafted and considered by ACPSEM Council and PSB
- Assumes
  - Experience in Nuc Med physics, acceptance testing and QC
- Concentrates on hands on experience and practice of PET acceptance testing and QC
  - Restricted numbers per course
- 2 day course – over weekend
  - Access to PET scanner, activity etc required
- Material for course being collated

Other items

- Guidance, supplementary documents and independent analysis S/W being developed
- Welcome involvement of Nuc Med physicists and community
  - ?Best channels of communication
- ACPSEM medical physicist register being finalised
- Document adoption by DoHA, ANZAPNM?
- Further details
  - ANZSNM Website
  - Contact Chair of TSC

NEMA NU2-2001 PET Scanner Acceptance Testing Notes

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These notes reflect experiences from recent acceptance testing of Siemens Biograph HiRez, Philips Gemini GXL (both local systems), and GE Discovery STE (overseas system). These notes reflect the views and experiences of the authors and may be of use for physicists planning acceptance tests. However, the notes are not for general circulation and should be requested from the authors on an individual basis.

Acknowledgement and Thanks

- Dale Bailey, Graeme O'Keefe and Steven Meikle for drafting updated version
- TSC Committee members for their hard work, input and insight
- ANZSNM Federal Committee for their support
- Groups, organisation and individuals who commented on and provided input to the document for their efforts and patience
- ACPSEM council, president and SG chair for furnishing information and clarifications on medical physics qualification requirements and ACPSEM processes.